



January 5, 2012

U.S. Nuclear Regulatory Commission, Region I
ATTN: Todd J. Jackson, Senior Health Physicist
475 Allendale Road
King of Prussia, PA 19406-1415

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SUBJECT: Response to a Notice of Violation - Lantheus MI Radiopharmaceuticals, Inc. San Juan and Ponce sites, Puerto Rico, Docket Nos. 03034187, 03038114, License No. 52-25361-01-MD

Dear Mr. Jackson:

This letter is to inform you of the corrective and preventive actions in Lantheus MI Radiopharmaceuticals, Inc. operations in San Juan and Ponce in response to your inspection on October 19, 2011 and the associated Notice of Violation. The following narrative describes your findings and our planned corrective and preventive actions.

Findings

- A. Failure to maintain complete records of the disposal of licensed materials as required by Condition 18.C of NRC License.

Reason for violation:

1. After an investigation was performed, the violation's root causes were identified. New personnel were assigned to manage waste shipments in 2008 and their transition coincided with a waste management procedure revision which included changes in the waste shipment registration form. Although the personnel were trained, the form was not properly completed because it was later found that employees got confused with the new form and did not ask for clarification on how to properly fill out the document. Another contributing factor was that the waste disposal task is not performed daily, and assigned employees failed to recognize the importance of proper documentation due to the lack of continuity. The improper documentation was not captured during internal audits. The audit forms available did not provide for an adequate waste shipment records review and management did not recognized the deficiencies on the audit checklist forms.

Corrective steps taken:

- 1. Waste Record form was updated to include survey meter S/N column and "reviewed by" section. See Appendix A: Radioactive and Biohazard Waste Disposal Log (attached).

2. Personnel directly involved in the waste management task were trained on October 20, 2011 on how to properly fill the form.
3. On October 26, 2011, the rest of pharmacy personnel were trained on waste management.
4. Senior staff reviewed all newly created waste record forms to ensure they were being properly filled out.

Full compliance was achieved by October 26, 2011.

Additional preventive actions to be taken to avoid further violations:

1. Review and if necessary revise the procedure in order to include clear instructions on how to perform the related duties.
2. The bi-annual internal audit procedure will be reviewed.

Date when full implementation of additional preventive actions will be achieved: by April 1, 2012.

- B. Failure to calibrate some radiation survey instruments as required by Condition 20 of NRC License.**

Reason for violation:

1. After an investigation was performed, the violation's root causes were identified. There was no effective system in place to keep track of survey meter calibration due dates.

Corrective Steps taken:

1. Survey instruments found to be in non-compliance were sent immediately for calibration.
2. New survey meters were acquired as spare units to allow for equipment malfunction, breakdown and/or when instruments are sent for calibration.
3. An inventory list was created for a complete accounting of all radiation survey equipment.
4. A new employee was assigned and trained to be in charge of equipment calibration verification.

Full compliance was achieved by November 18, 2011.

Additional preventive actions taken to avoid further violations:

1. Compilation of data was used in the development of a preventive maintenance Excel workbook that will track the calibration due date, location and status of all equipment that requires calibration. Monthly reports will be generated to monitor equipment status. The Radiation survey instruments calibration procedure will be updated.
2. Monthly verification of equipment calibration will be implemented.
3. All lab personnel will be refreshed on equipment calibration status awareness. Refresher training will be documented.

Date when full implementation of additional preventive actions will be achieved: by April 27, 2012.

As required in the Notice of Violation letter, a copy of this document will be sent to:

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Should you have any other questions please do not hesitate to contact our RSO, Eduardo Diaz, or our EHS Specialist, Angel Pagan, at (787) 765-5598, Ext. 2503, and Ext. 2518, respectively.

Sincerely,



Joel A. Cordero, RPh, BCNP
Director of Operation
Lantheus MI Radiopharmaceuticals, Inc.

