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

April 18, 2016

Docket No. 03038114 License No. 52-25361-02
Event No. EN51438

Eduardo Diaz, RPh.
Senior Manager of Operations
Lantheus Medical Imaging
150 Federico Costa Suite 1
San Juan, PR 00918-1303

SUBJECT: NRC INSPECTION REPORT NO. 03038114/2015001, LANTHEUS MEDICAL IMAGING, SAN JUAN, PUERTO RICO SITE

Dear Mr. Diaz:

From October 14, 2015 through April 6, 2016, Michael Reichard and John Miller 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 a dosimetry measurement for the monitoring period of August 2015, which could indicate a personnel overexposure, reported to the NRC on October 1, 2015, EN51438. The findings of the inspection were discussed with your organization at the conclusion of the inspection. The enclosed report presents the results of this inspection.

Within the scope of this inspection, no violations were identified.

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/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.

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).

No reply to this letter is required. Please contact Michael Reichard at 610-337-6945 if you have any questions regarding this matter.

Sincerely,

/RA/

Monica L. Ford, Acting Branch Chief
Commercial, Industrial, R&D and Academic Branch
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03038114/2015001

cc: Roy Greaves, Director, Environment, Health, and Safety
Commonwealth of Puerto Rico

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03038114/2015001
Docket No.	03038114
License No.	52-25361-02
Licensee:	Lantheus Medical Imaging
Location:	150 Federico Costa, Suite 1 San Juan, Puerto Rico 00918-1303
Inspection Dates:	October 14, 2015 through April 6, 2016
Date Followup Information Received:	November 2, 2015, December 11, 2015, and January 15, 2016

Inspectors:

/RA/ ***4/18/16***

Michael Reichard date
Health Physicist
Commercial, Industrial, R&D and Academic Branch
Division of Nuclear Materials Safety

/RA/ ***4/11/16***

John Miller date
Health Physicist
Commercial, Industrial, R&D and Academic Branch
Division of Nuclear Materials Safety

Approved By:

/RA/ ***4/18/16***

Monica L. Ford, Acting Branch Chief date
Commercial, Industrial, R&D and Academic Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Lantheus Medical Imaging
NRC Inspection Report No. 03038114/2015001

The inspection was a limited scope inspection focusing on a dosimetry measurement for the monitoring period of August 2015, which could indicate a personnel overexposure, reported to the NRC on October 1, 2015, EN51438.

An on-site inspection was conducted on October 14 and 15, 2015. The on-site inspection included interviews of appropriate licensee personnel, viewing live and pre-recorded reenactments, a review of applicable records, and a tour of the facility.

The inspectors reviewed the licensee's 30 day reports dated October 28, 2015, December 10, 2015, and January 14, 2016. The inspectors continued the inspection, in office until April 6, 2016.

The licensee, in coordination with Landauer, determined that most of the exposure to the dosimeter was due to the dosimeter being contaminated during a non-routine activity with an F-18 synthesizer. The licensee provided their calculations and other supporting documents, which were reviewed by the inspectors. The inspectors performed independent calculations and determined that the licensee's assumptions, calculations, and results were reasonable.

The licensee concluded that the individual's dosimetry results should be revised to a Whole Body DDE of 1.858 rem, an LDE of 1.929 rem, an SDE of 1.983 rem, a right extremity exposure of 23.62 rem, and a left extremity exposure of 19.85 rem for calendar year 2015.

The licensee committed to process, procedural, and training corrective actions regarding proper use of dosimetry, non-routine maintenance processes, surveying processes, and documentation.

No violations were identified.

REPORT DETAILS

I. Program Overview

The Nuclear Regulatory Commission (NRC) License No. 52-25361-02 authorizes Lantheus Medical Imaging (Lantheus) to produce, possess, handle, and distribute radiochemicals and for transfer to persons authorized to receive the licensed material. Specifically, Lantheus produces the radioisotope Fluorine 18 (F-18). Typically, Lantheus produces F-18 five nights per week, two runs per night. Additionally, Lantheus possesses incidentally activated products and sealed sources for calibration and the checking of instruments.

II. Dosimeter Overexposure Event Summary and Inspection Findings

a. Inspection Scope

The inspection was a limited scope inspection focusing on a dosimetry measurement for the monitoring period of August 2015, which could indicate a personnel overexposure, reported to the NRC on October 1, 2015, EN51438.

The inspection was performed in accordance with Inspection Procedure 87103, "Inspection of Material Licensees Involved in an Incident or Bankruptcy Filing." The Focus Elements addressed were 05.01 through 05.14. The inspectors performed an onsite inspection on October 14 and 15, 2015, which included a review of dosimetry records and daily cyclotron running logs, viewing a video reenactment, observing a live reenactment, interviewing applicable licensee staff, and a tour of the licensee's facility.

The inspectors discussed irregularities with the dosimetry result with the licensee and a Landauer representative during a telephone conversation on October 19, 2015. The inspectors reviewed the licensee's event report, dated October 28, 2015, which was received on November 2, 2015. The inspectors discussed the event report with licensee representatives on November 13, 2015. The licensee elected to amend their report. The inspectors reviewed the amended event report dated December 10, 2015, received on December 11, 2015. The inspectors discussed the event report with the licensee, and the licensee elected to write a second amendment. The second amendment to the event report, dated January 14, 2016, was received on January 15, 2016.

b. Observations and Findings

During the on-site inspection, conducted on October 14 and 15, 2015, the inspectors reviewed the work history of the individual that received the high result. The licensee provided a detailed log book. During the month of interest, the individual did not perform non-routine maintenance, such as a target replacement or repair, on the cyclotron. One logbook entry was of particular interest, because it involved trouble shooting inside the Explora synthesizer module (Explora). The Explora entry was noted in the logbook as "high exposure," but the exposure rates were not logged. Additionally, the individual stated that, during August of 2015, he performed routine tests called "QC Tests" and "Sterility Tests." These tests were routine and involved smaller quantities of radioactive

material. The licensee considered these tests as potential procedures that could result in a contamination event, but concluded that the non-routine operations with the Explora was the more likely scenario to produce the elevated dosimetry reading. This was considered likely when considering either an external radiation event or a contamination event.

The inspectors observed a recorded reenactment of the non-routine Explora activity. The inspectors requested a live reenactment of the Explora activity, the QC test, and the sterility test. The reenactment was effective at establishing reasonable time/motion assessment and enabled the inspectors to determine the distance from the dosimeters to significant radiation sources. The licensee provided external radiation calculations based on the Explora activity. The inspectors determined that even with conservative assumptions, the reported dosimetry exposure was difficult to justify by an external radiation exposure. These calculations were reviewed in greater depth after the inspection during the review of the licensee's 30 Day event reports. Though the calculations were more refined, the conclusion was the same.

The licensee presented a report from Landauer, which explained that the exposure to the dosimeter was irregular. It explained that there are four active regions within the dosimeter, each of which has a different filter. One of the active regions was noticeably higher than the other regions with another region slightly less than the remaining two. Specifically, the results were 12.2 rem, 7.7 rem, 7.5 rem, and 6.6 rem. Following the on-site inspection, during a conference call on October 19, 2015, Lantheus and the inspectors discussed these irregular results with a Landauer Health Physicist, who is also Landauer's Director of Technical Services. She explained that it was her technical position that the most likely cause of the irregular exposure was contamination on the dosimeter. Further, she provided a letter dated October 21, 2015, that explained the irregular exposure and how the four regions within the dosimeter work. Based on this information from Landauer, Lantheus concluded that most of the dosimeter's exposure was likely due to contamination to the dosimeter.

During the tour and reenactments conducted on October 14, 2015, the inspectors observed that the authorized users' dosimeters were stored in the same area as licensed operations. Though not ideal, the authorized users could remove their whole body dosimeters prior to removing their gloves or surveying their hands for contamination. This fact presented the reasonable possibility that a dosimeter could be removed with contaminated gloves, followed by the removal of the contaminated gloves, followed by surveying the individual's hands, which would not be contaminated. A dosimeter could be contaminated without immediate discovery. Interviews of the licensee's staff concluded that small spot contamination on the fingertip of gloves did sometimes happen during unusual entry into the Explora. However, these unusual entries into the Explora only happen approximately twice per year.

Lantheus concluded that the most likely scenario was that the individual received a small spot contamination on his gloves during the non-routine Explora entry. The individual removed his dosimeter and placed it on his desk, removed his gloves, and surveyed his

hands for contamination. He determined that his hands were not contaminated. Accordingly, Lantheus proposes revising the individual's whole body and extremity exposures for 2015.

c. Dose Assessment – External Whole Body Exposure

Lantheus initially assumed that the dosimetry result was due to external exposure during the non-routine operation with the Explora, because it was the most conservative assumption. Lantheus health physicists established assumptions learned from the reenactments, including distance, time, and activity. Lantheus calculated that the most likely external exposure to the individual was 862 mrem. The assumptions, calculations, and result were documented in the second amendment of their 30 day report, dated January 14, 2016.

The inspectors independently performed similar calculations and confirmed that the result of 862 mrem was reasonable. They further challenged the calculations by applying unrealistically conservative assumptions and determined that it was unreasonable that the entire dosimetry result could have been the result of an external exposure to the dosimeter during the non-routine operation on the Explora.

The inspectors determined that an external, whole body exposure of 862 mrem was reasonable.

d. Dose Assessment – Dosimetry Contamination

Lantheus, with agreement from Landauer, assumed that the remaining dosimetry result, 6.9 rem, was likely due to contamination to the dosimeter. Lantheus calculated the activity needed to result in this exposure to be 0.077 mCi. Lantheus provided the calculations and assumptions to the NRC in the second amendment of their 30 day report, dated January 14, 2016.

The inspectors independently performed similar calculations with Varskin and Microshield and determined that the results presented by Lantheus were reasonable.

e. Dose Assessment – Extremity Exposure

Lantheus determined that the contamination of the dosimeter was most likely transferred from one of the individual's fingertips. They further recognized that the initial activity on the glove was likely greater than the activity that was transferred to the dosimeter. Though the activity assumed to be on the dosimeter was calculated to be 0.077 mCi, Lantheus conservatively assumed that the initial activity on the glove was 1.06 mCi. This conservatively accounts for a relatively low transfer rate and the possibility that some of the activity was transferred elsewhere. The licensee's calculations and assumptions are documented in Lantheus' second amendment to their 30 day report, dated January 14, 2016. Lantheus calculated that this could result in 16.7 rem to the employee's extremity.

The inspectors independently performed similar calculations with Varskin and determined that the results presented by Lantheus were reasonable.

f. Dose Assessment – Revised Dose Record

Based on the calculations discussed above, Lantheus has proposed to revise the individual's dose record.

The licensee determined that the individual's whole body deep dose equivalent, lens dose equivalent, and shallow dose equivalent for August, 2015, should be revised to 1,000 mrem. This includes 862 mrem for the non-routine activity and 138 mrem, based on the average results the individual normally receives during a month.

The licensee determined that the individual's extremity exposure should be increased by 16.7 rem for August, 2015.

After all adjustments, the individual's dose record for the year would be Whole Body DDE, 1.858 rem; LDE, 1.929 rem; SDE, 1.983 rem; right extremity, 23.62 rem; and left extremity, 19.85 rem.

g. Corrective Actions

Though Lantheus determined that an overexposure did not occur, the licensee recognized that their processes and procedures needed further refinement to prevent recurrence. The licensee has developed new site-specific procedures and training on those procedures.

The licensee established a new dosimetry storage location outside of the radiative material use area. The new procedures include specific instructions on the proper handling, use, and storage requirements for personnel dosimetry. The procedures require written radiation measurements and dose assessments prior to performing non-routine activities. A procedure was created, specifically detailing all requirements for performing non-routine operations on the Explora. The licensee has added additional survey and record keeping requirements for non-routine activities.

A list of the corrective actions was provided in the second amendment to their 30 day report, dated January 14, 2016. The inspectors determined that the corrective actions were appropriate.

h. Conclusions

The inspectors reviewed all aspects of the licensee's investigation regarding the elevated dosimetry result, including their calculations, and determined that the licensee's assessment was an appropriate balance of conservativism and reasonableness. The inspectors performed independent calculations and determined that the licensee's investigation results were reasonable. The inspectors reviewed the licensee's corrective actions and determined that they were appropriate and comprehensive.

No violations were identified.

III. Exit Meeting

The inspectors reviewed the inspection results with you during an exit meeting conducted on April 6, 2016.

SUPPLEMENTAL INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Licensee

David Brown, Senior Health Physicist
William Dawes Jr., Vice President of Manufacturing and Operations
Eduardo Diaz, RPh, Senior Manager of Operations and Radiation Safety Officer
Roy Greaves, Director, Environment, Health, and Safety
Julie Hanlon, Senior Health Physicist
Justin Harpin, Radiation Protection Technician
Angel G. Pagan, EHS Specialist

Landauer

Mirela Kirr, Director, Technical Services

INSPECTION PROCEDURES USED

87103	Inspection of Material Licensees Involved in an Incident or Bankruptcy
87125	Materials Processor/Manufacturer Programs
87127	Radiopharmacy Programs

LIST OF DOCUMENTS REVIEWED

Event Notification Report: EN51438
Event Reports Dated October 28, 2015, December 10, 2015, and January 14, 2016
Landauer Radiation Dosimetry Reports, January 2013, through September 2015
Daily Cyclotron Running Logs, January 2015, through October 2015
Landauer Report, dated October 21, 2015, “Review of Dose Assessment for Participant 16416, Wear Date 08/01/2015”