

**U.S. NUCLEAR REGULATORY COMMISSION****Date:**

1/14/2013

**TELEPHONE CONVERSATION RECORD****Mail Control  
or Report No(s).****License No(s).**

52-25361-01MD

**Docket No(s).**

03034187

**Name of Licensee:**

Lantheus MI Radiopharmaceuticals

**Name of Participant(s):**Eduardo Diaz, Lantheus  
Todd Jackson, USNRC Region I**Telephone No.**

Eduardo office: 787-765-5598, ext 2503

**Subject:**

Customer complaints about Cardiolite dosages that did not produce expected/desired imaging results.

(NOTE: This will be used as the Documents Title in ADAMS)

Eduardo called to inform NRC about an issue identified last week with Lantheus' quality of shipped Cardiolite doses on Tues, January 8, 2013. Lantheus got phone calls from several customers (starting at about 7 AM on 1/8/13) informing them that imaging did not show the heart as expected or typical for such doses, instead illuminating different parts of the patients' bodies. Quality control (QC) checks at Lantheus prior to shipment had shown the doses to be acceptable, and when they re-ran QC checks later in the day after the phone calls came in they had indication of deterioration in the quality of the material. All doses had the correct quantity of Tc-99m in them, but the pharmaceutical reagent was questionable.

Multiple customers were impacted, at least 10. Three lots from the prepared batch of Cardiolite were determined to be unacceptable when re-tested later on Jan 8. While not clear what went wrong with the lots, it appeared to Lantheus that something had deteriorated in the prepared materials. Eduardo had called my phone number on Wed Jan 9 (my phone log shows that he called at 0813) but he did not leave a message and did not try to call anyone else in Region I. Eduardo stated that Lantheus had concluded that no NRC report is required as a result of this issue, and I cannot find any requirement for a report either.

**Action Required: None****Document Availability:****Publicly Available****Non-Publicly Available****Non-Sensitive****Sensitive – Privacy Act/ PII****Immediate Release****Non-Sensitive Copyright****Sensitive – Internal****Normal Release Date: 01/223/2013****Sensitive- Proprietary****Sensitive – Security-Related****Delayed Release Date:****SUNSI Review Completed By:**

TJackson

/ RA /