

From: Dwyer, James
Sent: Tuesday, May 17, 2011 9:43 AM
To: Lorson, Raymond
Cc: Collins, Daniel; Ferdas, Marc
Subject: Lantheus Medical Imaging (radiopharmacy) - HOO report

This morning I spoke with Eduardo Diaz, R.Ph. and Manager of the Lantheus Radiopharmacy in San Juan.

Diaz said that Advanced Techno-Nuclear (LN 52-25340-01) in San Juan ordered a dose of indium-111 DTPA for a diagnostic brain study. On Friday, May 13, Lantheus mistakenly shipped a dose of IN-111 oxine to Advanced Techno-Nuclear and the physicians at Advanced Techno-Nuclear administered the dose. IN-111 oxime is used to label white blood cells. Diaz said that Lantheus labeled the shipment as containing 600 microcuries of IN-111 DTPA when it was actually 600 microcuries of IN-111 oxine.

Diaz said he calculated a whole body dose of less than 5 rad and a maximally exposed organ dose of less than 50 rad. I confirmed these exposures using the package insert for IN-111 oxine (0.372 rad WB and 15.6 rad spleen). Diaz said he believes he did not need to report the event and I confirmed his understanding of the regulations in 10 CFR 35.3045. Diaz was going to retract the HOO report. Diaz said they had already entered the event into their corrective action program and would take actions to improve their process to prevent it from occurring in the future.