



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

September 17, 2012

Docket No. 03034187  
Control No. 577655

License No. 52-25361-01MD

Joel Cordero, R.Ph.  
Associate Director of Operations  
Lantheus MI Radiopharmaceutics, Inc.  
150 Federico Costa St., Suite #1  
San Juan, PR 00918-1303

SUBJECT: LANTHEUS MI RADIOPHARMACEUTICS, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 577655

Dear Dr. Cordero:

This is in reference to your letter dated May 24, 2012 requesting to amend Nuclear Regulatory Commission License No. 52-25361-01MD. In order to continue our review, we need the following additional information:

1. Please provide the information requested under the "Response from Applicant", NUREG-1556 Vol. 13, Item 8.6.1 for your redistribution activities.
2. Your current license indicates you are authorized to provide calibration services for outside clients. Please provide specific procedures for all service activities and include information on the minimum qualifications that will be acceptable for those performing those services.
3. Please provide a copy of your Pharmacy registration or license.
4. Please identify all sealed sources that you would like listed on your license to be authorized for distribution to 10 CFR 35.400 and 35.500 users. Please indicate the manufacturer and model number for each sealed source.
5. Although you have indicated that dose measurement system checks and tests will meet the requirements in 10 CFR 32.72 you did not describe the actual systems you will use to measure the dosages. Please provide a description of what systems you use and include any beta emitting byproduct materials that you may intend to distribute for their beta dose. How will beta systems be calibrated?

Current NRC regulations and guidance are included on the NRC's website at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits, see our toolkit index page**. 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.

J. Cordero

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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.

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 577655. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5303.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

***Original signed by Thomas K. Thompson***

Thomas K. Thompson  
Senior Health Physicist  
Commercial and R&D Branch  
Division of Nuclear Materials Safety

cc:  
Eduardo Diaz Montes, R.Ph., Radiation Safety Officer

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**SUNSI Review Complete: TThompson**

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