



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 6, 2012

Docket No. 030-38114
Control No. 144073

License No. 52-25361-02

Joel Cordero
Associate Director
Lantheus Medical Imaging
Suite 1
150 Federico Costa
San Juan, PR 00918-1303

SUBJECT: LANTHEUS MEDICAL IMAGING, REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL
NO. 144073

Dear Mr. Cordero:

This is in reference to the electronic mail dated December 22, 2011, received from Peter Fipphen, Director, Taxation and Treasure for Lantheus Medical Imaging, Inc., transmitting the auditor's letter in support of financial assurance for Nuclear Regulatory Commission License No. 52-25361-02. The financial assurance instrument still is not complete.

In order to continue our review, we need the following additional information:

1. The decommissioning funding plan (DFP) and cost estimate was prepared by your consultant in April 2009. The cost estimate based on this DFP was considered acceptable by the NRC, and we requested that you submit the financial assurance instrument in the amount of that cost estimate in letter dated December 10, 2009. The NRC regulations in 10 CFR 30.35(e) require that cost estimates be adjusted at 3 year intervals. Confirm that you will review your cost estimate in 2012 and submit new documents to support your financial assurance if the amount increases.
2. A letter dated March 31, 2010, transmitted the following documents in support of your financial assurance: A Surety Bond dated March 15, 2010; acknowledgement of the Surety; and a Certification of Financial Assurance (CFA). In emails dated May 19 and 26, 2010, we informed you that the CFA required revision, and a Standby Trust Agreement was needed to complete the financial assurance instrument. The revised CFA was submitted on May 24, 2010.

In June 2010, the responsibility for completing the financial assurance was turned over to Peter Fipphen in the Lantheus main office in Massachusetts. At that time, the corporate office decided to change the financial assurance instrument to a Parent Company Guarantee. The following documents were received to date in support of the Parent Company Guarantee:

Certification of Financial Assurance dated May 21, 2010 submitted with the letter dated May 24, 2010

Chief Executive Officer letter dated March 7, 2011, received by email on December 8, 2011

Chief Financial Officer Letter dated March 7, 2011, received by email on December 8, 2011

Auditor's special report dated March 7, 2011, received by email on December 22, 2011

- a. The documentation required for use of a parent company guarantee as a financial assurance instrument is not yet complete. Provide the following documents required to complete the Parent Company Guarantee as described in NUREG-1757, "Consolidated NMSS Decommissioning Guidance", Volume 3, "Financial Assurance, Recordkeeping, and Timeliness" (NUREG-1757, Vol. 3), Appendix A.13, "Parent Company Guarantees":
 - i. The parent company guarantee agreement, originally signed duplicate. A model parent company agreement can be found in NUREG_175, Vol 3., Appendix A.13.10.
 - ii. The parent company's audited financial statements for the most recent fiscal year, including the auditor's opinion of the financial statements.
 - iii. The standby trust agreement with all supporting documentation, as described in NUIREG-1757, Vol. 3, Appendix A.17
 - b. In accordance with Appendix A.II.C of 10 CFR Part 30, the parent company must repeat the passage of the financial test within 90 days of the close of each succeeding fiscal year. The financial tests submitted were for the year that ended December 31, 2010. Confirm that you will perform the tests within 90 days of your most recent fiscal year, and send a notice to the Commission if you no longer meet the applicable requirements and will establish new financial assurance.
3. At this time, you are not in compliance with NRC regulations that require you to provide a financial assurance in the amount of the cost estimate using an approved method. At this time, we have the cost estimate for decommissioning and a certification statement as required by 10 CFR 30.35(e). However, we do not have a completed and signed original financial instrument. An incomplete financial instrument using a Surety bond was submitted in March 2010; the change to using a Parent company Guarantee occurred in June 2010 but the documentation for this instrument is in progress for 18 months and not yet complete. Provide a schedule by which you expect to complete submission of a financial assurance instrument. Continued failure to come into compliance could be considered for escalated enforcement.

Current NRC regulations and guidance are included on the NRC's website at 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

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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).

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. 144073. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040.

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 Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:

Eduardo Diaz, Radiation Safety Officer
Peter J, Fipphen, Director, Taxation and Treasure

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