

From: [Nguyen, Janice](#)
To: James.Bradosky@lantheus.com; [Plourde, Laura K](#)
Cc: [Glen Palmer](#); eduardo.diaz-montes@lantheus.com
Subject: NRC Request for Additional Information for Lantheus Medical Imaging and Lantheus MI Radiopharmaceuticals, Inc. (Mail Control Numbers 624028 and 624029)
Date: Friday, January 8, 2021 2:54:00 PM

Licensee: Lantheus Medical Imaging
License No.: 52-25361-02
Docket No.: 030-38114
Control No.: 624028

Licensee: Lantheus MI Radiopharmaceuticals, Inc.
License No.: 52-25361-01MD
Docket No.: 030-34187
Control No.: 624029

PLEASE CONFIRM RECEIPT OF THIS REQUEST FOR ADDITIONAL INFORMATION BY RETURN EMAIL

Dear Mr. Bolla and Mr. Palmer:

This is in reference to your letter dated December 10, 2020, regarding a direct transfer of control of Nuclear Regulatory Commission (NRC) License No. 52-25361-02 and indirect transfer of control of Nuclear Regulatory Commission License No. 52-25361-01MD to PharmaLogic Holdings Corp. In order to continue our review, please provide the following additional information:

1. Lantheus Medical Imaging (NRC License No. 52-25361-02) appears to be going through two separate transfers of control. Lantheus US will be directly transferring the license to Lantheus MI and then Lantheus MI will be indirectly transferring the license to PharmaLogic Holdings. However, your letter dated December 10, 2020 does not provide any information on the initial direct transfer between Lantheus US and Lantheus MI.

Please provide a complete description of the transfer of control between Lantheus US and Lantheus MI, and indicate these changes on your pre- and post-transaction organizational charts. Please see Appendix E of NUREG-1556, Volume 15, Rev. 1, "Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses" for required information.

Please note that once this additional information is received, the request will need to be reposted to the NRC website for public comment. The new information will be posted for 30 days.

2. Lantheus Medical Imaging (NRC License No. 52-25361-02) is subject to having financial assurance in place, which currently includes the following documents:

Certification of Financial Assurance dated September 22, 2020 [ML20294A229]
Surety Bond dated March 2, 2017 [ML17080A340], Surety Bond Rider dated April 3,

2020 [ML20135H156]

Standby Trust Agreement dated August 24, 2012 [ML12265A067], Standby Trust

Agreement Amendment dated October 16, 2020 [ML20337A068]

Decommissioning Cost Estimate dated April 29, 2019, but revised and re-submitted with email dated April 28, 2020 [ML20119B001]

In your letter dated December 10, 2020, you indicated that the amount and the details of the revised DFP will not change as a result of the transfer, but PharmaLogic will submit a revised DFP within 30 days to reflect the change in ownership. You did not address the other financial documents that will be changed as a result of the transfer.

Please confirm that that all financial assurance instruments will be held in the transferee's name before the license is transferred. Please also provide draft documents of PharmaLogic's financial assurance package.

3. In your letter dated December 10, 2020, Attachment 1, Item 7, you indicated that the applicants were not aware of any open inspection items and/or enforcement actions, but PharmaLogic will accept responsibility for any open inspection items and/or any resulting enforcement actions.

Please confirm that PharmaLogic Holdings Corp. is aware that Lantheus Medical Imaging received two Severity Level III violations and were subject to a civil penalty of \$7,500 for an inspection conducted by the U.S. Nuclear Regulatory Commission (NRC) on February 14, 2018, March 7, 2018, and April 10, 2018, with continued in-office review through November 13, 2019, at the Lantheus Medical Imaging (LMI) facilities in Billerica, Massachusetts and San Juan, Puerto Rico and an associated NRC investigation completed on June 6, 2019. The violations were issued in Enforcement Action (EA-19-068) dated April 23, 2020, and the civil penalty was paid in May 2020.

If you or your representatives have any questions, please feel free to contact me. We will continue our review upon receipt of the requested information. You may respond to my attention in writing by letter, email (if letter is signed by senior management of all involved entities and scanned into a pdf format), or fax (610-337-5269), referencing mail control numbers 624028 and 624029. Please submit a reply within 30 days. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5006.

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 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).

Thank you in advance for your help!

Jan

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