

From: [Ullrich, Elizabeth](#)
To: [Hayes, James](#)
Cc: [Diaz, Eduardo](#)
Subject: Additional information needed RE: Lantheus Puerto Rico Authorized User Amendment Request
Date: Monday, September 24, 2018 9:04:00 AM
Attachments: [image001.png](#)

Mr. Hayes,

The letter dated September 21 states that both have a background in cyclotron work. Based on the training and experience records submitted, I note that Jose Ramos has been working for about 10 years operating the cyclotron and radiosynthesis system, and performing maintenance of the cyclotron and cyclotron facility. Bryan Fernandez has worked there for a little more than 2 years, working in the PET laboratory, as a cyclotron operator and in PET QC, performing QC and maintenance of the cyclotron.

1. For each of the proposed authorized users, provide more specific information about the activities they performed as a cyclotron operator and the activities they performed for maintenance of the cyclotron. Where possible, specify the amount of time and/or frequency of performing such activities. For example, how often (or how much time) has each spent preparing targets and rebuilding targets? How much experience has each had with effluent monitoring and performing other surveys?
2. Your letter lists 8 specific cyclotron training activities that you believe are pertinent to support site specific cyclotron operation and maintenance, but does not state which of these training activities either of the individuals participated in, or when the training was received. It does not specify the amount of time spent on each of these topics nor who provided the instruction. Please provide more specific information for this training, and when each of these individuals attended this training. In addition, explain why training in the "Handbook of Radiation Protection" and "HAZMAT Transportation" is considered "not applicable".
3. It does not appear that either of these individuals attended training provided by the manufacturer of the cyclotron, or equivalent training. Your previous authorized user had 10 days of introductory training by the manufacturer, and 10 days of advanced training.
 - a. Confirm when/if you plan to provide the manufacturer's training (or equivalent) to either or both of the individuals proposed to be named as authorized users. In particular, we are concerned with activities related to safe handling of licensed materials, including activities with targets (routine handling, trouble-shooting, re-building, etc.) and activities during radiosynthesis (routine production and handling of incidents during synthesis).
 - b. Provide your plan for providing activities required for servicing, preventive maintenance, corrective maintenance, and system troubleshooting until you have authorized users that have manufacturer's (or equivalent) training.

Please provide your response in a signed letter. You may submit the letter as a pdf attachment to an email to me. Please refer to Control No. 609969. If you have any

questions, please email me or call me at 610-337-5040. Thanks,

Betsy

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From: Hayes, James [mailto:James.Hayes@lantheus.com]
Sent: Friday, September 21, 2018 3:41 PM
To: Ullrich, Elizabeth <Elizabeth.Ullrich@nrc.gov>
Cc: Gordon, Craig <Craig.Gordon@nrc.gov>; Diaz, Eduardo <Eduardo.Diaz-Montes@lantheus.com>
Subject: [External_Sender] Lantheus Puerto Rico Authorized User Amendment Request

Dear Ms. Ullrich:

Earlier today I left you a voicemail regarding my phone conversation with Mr. Craig Gordon. Mr. Gordon and I discussed concerns with the Operations License No. 52-25361-02 for Lantheus MI Pharmaceuticals, Inc. (LMI-PR). It was not the understanding of LMI-PR that this Amendment was needed to be filed immediately. As a result of my conversation with Mr. Gordon LMI-PR immediately halted production operations on Thursday (20 September 2018) and has submitted this Amendment Request for expedited review by the NRC.

The expedited review has been requested in order for us to continue to safely produce and serve patients as the only provider of Fludeoxyglucose (F-18) in Puerto Rico. As we produce F-18 Sunday – Friday each week we request approval to resume production operations no later than Monday afternoon (24 September 2018).

We believe the attached Amendment Request Letter and supporting documentation demonstrate the individuals meet the qualifications as Authorized Users.

Please feel free to contact me with any questions or to discuss the Amendment request in greater detail. I greatly appreciate your timely support in this review and approval process.

Best regards,

James Hayes
Sr. Director EH&S and RPO

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