

## Parker, Bryan

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**From:** Parker, Bryan  
**Sent:** Friday, October 20, 2017 5:25 PM  
**To:** 'manuel.diaz@curiumpharma.com'  
**Subject:** Request for Additional Information - CN601370  
**Attachments:** Mallinckrodt -01 Th227 amend 601370 RAI.docx

Hey Manuel,

Attached is a Request for Additional Information (RAI) for the Th-227 amendment request.

As discussed, you may respond via email by attaching the response as a **signed** PDF file and sending it to me. Please mark the response as "**Additional Information for CN601370**".

If you prefer (or the file size seems too big), please simply mail it to the Region III office marked the same way (address is in sig block below).

Please let me know if you have any questions.

Thanks.  
Bryan

*Bryan A. Parker*

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**Request for Additional Information**

**Mallinckrodt Nuclear Medicine, LLC**  
**Maryland Heights, MO (CN 601370)**

1. In Section A.2. of your letter dated October 4, 2017, you indicate that "all activities will be conducted in the Maryland Heights facility."

Please further describe where and how these activities involving use of thorium-227 (Th-227) will be conducted.

2. In Section A.2. of your letter dated October 4, 2017, you indicate that "Stack emissions will be continuously monitored to estimate environmental emissions" and "Triggered alarms are established to indicate when stack releases above a critical value are detected."

Please further describe how this monitoring will be accomplished. What isotope(s) will you be monitoring for? What are the trigger levels and how are they established? What is the minimal detectable activity (MDA)?

3. In Section A.3. of your letter dated October 4, 2017, you describe your bioassay monitoring for Th-227.

Is this routine monitoring? If so, what is the frequency and what are the action levels?

4. In Section A.4. of your letter dated October 4, 2017, you indicate "area air samples will be collected daily when working with Th-227 using continuous air monitors (CAM)." Also, in Section A.7., you indicate CAMs will be used in monitoring of waste.

Please further describe how this monitoring will be accomplished. What isotope(s) will you be monitoring for? What are the trigger levels and how are they established? What is the minimal detectable activity (MDA)?

5. In Section A.5. of your letter dated October 4, 2017, you discuss training of workers who will handle Th-227.

Who will be providing this specialized training? Please provide further description of this specific training, as well as documentation of the trainers' training and experience related to Th-227 use.