

Parker, Bryan

From: Parker, Bryan
Sent: Friday, January 12, 2018 11:35 AM
To: 'scott.surovi@mallinckrodt.com'
Subject: Request for Additional Information
Attachments: Mallinckrodt 24-17450-01 601489 RAI.docx

Hey Scott,

Attached is a Request for Additional Information (RAI) for the amendment request to downgrade to a Type B broad. A response back to me by COB on Friday Jan. 19 would be greatly appreciated.

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 CN601489**".

Please let me know if you have any questions.

Thanks.
Bryan

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Request for Additional Information

Mallinckrodt, LLC - Hazelwood, MO (CN 601489)

- 1) With regard to Items 5 & 6 of your application dated 10/26/17, please confirm that along with the proposed possession limits, you will further restrict the possession of licensed material to quantities below the minimum limit specified in 10 CFR 30.35(d) for establishing decommissioning financial assurance.
- 2) With regard to Item 9 of your application dated 10/26/17, under "Facilities and Equipment", please provide the criteria the RSO will use to review and approve facilities and equipment (research laboratories, iodination facilities, waste storage facilities, survey and counting equipment, etc.).

For reference, please see 10 CFR 33.14(b)(2) and also Section 8.9 of NUREG-1556, Vol. 11, Rev. 1 (specifically, Pages 8-25 thru 27).

- 3) With regard to Item 10 of your application dated 10/26/17, under "Audit & Review of Program", please:
 - A) clarify the frequencies of "quarterly" and "annual";
 - B) confirm that audits will be unannounced and performance-based to the extent possible; and
 - C) confirm that audits will include elements such as those described in the NUREG-1556, Vol. 11, Rev. 1 guidance document.

For reference, please see Section 8.10.1 of NUREG-1556, Vol. 11, Rev. 1 (specifically, Pages 8-27 thru 29).

- 4) With regard to Item 10 of your application dated 10/26/17, under "Material Receipt & Accountability", please provide confirmation that you will develop, implement and maintain procedures for ensuring accountability of licensed materials at all times.

For reference, please see 10 CFR 33.14(b)(2) and also Section 8.10.3 of NUREG-1556, Vol. 11, Rev. 1 (specifically, Pages 8-31 thru 35).