



January 22, 2018

Brian Parker, Senior Health Physicist
Materials Licensing Branch
U. S. Nuclear regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

RE: Materials License Number 24-17450-01

ADDITIONAL INFORMATION for Control Number 601489

Dear Mr. Parker:

Pursuant to your January 12, 2018 request to Scott Surovi via electronic communication, Mallinckrodt LLC provides supplemental information in support of the pending October 26, 2017 license amendment application. The following responses are presented in the sequence associated with your electronic communication:

1. In addition to adherence to the radioactive material possession and uses described in Items 5 and 6 of our license amendment application, Mallinckrodt LLC 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. The Radiation Safety Officer (RSO) shall review all requests for new and modifications to facilities and equipment based on the criteria included with the July 1, 2015 license renewal application (Item 9 – Facilities and Equipment, pages 18 through 24) specifically addressing:
 - Facility classification scheme
 - Animal housing
 - Laboratory design
 - Radioisotope containment
 - Ventilation system
 - Waste management
 - Receiving and storage
 - Laboratory hoods/glove boxes

The RSO shall document the review and approval of all requests for new and modification to facilities and equipment to include the above described criteria, and make available for inspection upon request.



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3. With regard to the "Audit and Review of Program" portion of our license amendment application (Item 10 – Radiation Safety Program, page 5), the following is provided for your review:
 - a. Clarification:

The term "quarterly" in this context means a period of time equal to one-fourth of the year (approximately 13 consecutive weeks).

The term "annual" in this context means a period of time equal to 365 consecutive days coinciding with the start of a new calendar year.
 - b. Confirmation that annual audits of the Radiation Protection Program will be unannounced and performance-based to the extent possible.
 - c. Confirmation that annual audits of the Radiation Protection Program will include elements such as those described in NUREG-1556, Volume 11, Revision 1 (Appendix F) as applicable to radioactive material use and site operations.
4. With regard to Section 10 – Radiation Safety Program: Material Receipt and Accountability (pages 5 and 6 of the October 26, 2017 license amendment application), Mallinckrodt LLC confirms that procedures for ensuring accountability of licensed material at all time shall be developed, implemented and maintained.

I trust the supplemental information detailed above satisfies your concerns raised during the review of our October 26, 2017 license amendment application. Please contact Scott Surovi at (314) 654-7444 or scott.surovi@mallinckrodt.com for additional information.

Sincerely,

Richard Fitch, Ph.D.
Director Pharmacology
Mallinckrodt Research and Development