November 21, 2014

Ms. Karen Burke, Director
Environmental Remediation
Mallinckrodt Pharmaceuticals
675 McDonnell Boulevard
St. Louis, MO 63042

SUBJECT: REVISED REQUEST FOR ADDITIONAL INFORMATION ON THE FINAL STATUS SURVEY REPORTS FOR THE PHASE II DECOMMISSIONING PLAN. MALLINCKRODT COLUMBIUM-TANTALUM PLANT, SOURCE MATERIAL LICENSE STB-401

Dear Ms. Burke:

A public meeting was held between the U.S. Nuclear Regulatory Commission (NRC) and Mallinckrodt on October 9, 2014 to discuss the NRC staff's Requests for Additional Information (RAI) (Agencywide Document Access and Management System [ADAMs] Accession No. ML14175A305). These RAIs were related to Mallinckrodt's Final Status Survey Reports for the Columbium-Tantalum Plant (ADAMS Accession No. ML14177A180). During this meeting, Mallinckrodt requested clarification about whether the list of survey units in General Comment 1 should have included Survey Unit 4 (SU4). The NRC staff reviewed the RAI and found that SU4 should not have been included in the list of applicable survey units in General Comment 1.

Additionally, during the staff's review of the RAIs, the staff identified that General Comment 2 did not include all relevant survey units. General Comment 2 is applicable to all dose assessments included in the FSS, not only the dose assessment performed for SU22.

Based upon the staff reviews noted above, the staff has revised General Comments 1 and 2. The revised RAIs are provided in Enclosure 1 of this letter.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of the NRC's ADAMS. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

If you have comments or questions regarding this letter, please contact Karen Pinkston at 301-415-3650 or Karen.Pinkston@nrc.gov.

Sincerely,

/RA/

Michael Norato, Ph.D., Branch Chief
Materials Decommissioning Branch
Division of Decommissioning, Uranium Recovery,
and Waste Programs
Office of Nuclear Material Safety
and Safeguards

Docket No.: 40-6563
License No.: STB-401

Enclosure:
Request for Additional Information, Rev 1

cc: Mallinckrodt Distribution List

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U.S. Nuclear Regulatory Commission
Request for Additional Information on the Reports Entitled
"Phase II Final Status Survey Report, Chapters 1 through 33,
Mallinckrodt Columbium-Tantalum Plant, St Louis, Missouri"
Source Materials License No. STB-40-1475, Docket No. 40-6563
Revised General Comments 1 and 2

General Comments

1) **Comment:** In several survey units (e.g. SU1, SU2, SU5, SU6, SU10), Mallinckrodt was unable to remove all contaminated soil due to the close proximity to structural foundations. Demonstrate that any residual contamination beneath these structural foundations will meet the U.S. Nuclear Regulatory Commission's (NRC) unrestricted release criteria stated in Title 10, Code of Federal Regulations (CFR), Part 20, Subpart E, 20.1402.

2) **Comment:** The dose assessments performed are not adequately supported and may underestimate the potential dose from residual contamination. Specific areas that need additional justification are identified below. The below comments focus on the dose assessment performed for SU22. However, these comments are also potentially applicable to other survey units for which a dose assessment was performed (e.g., SU6, SU11, SU12, SU18, and SU20).

   a) In Chapter 28, Section 28.5.3.1 states that the Residual Radioactivity models (RESRAD) used to calculate this dose were identical to those used to develop the derived concentration guideline level (DCGLs). However, the DCGLs were based on probabilistic RESRAD calculations, while the dose assessment for SU22 was a deterministic calculation. Justification is needed for the use of the deterministic model and its associated parameters or a dose assessment that is identical to the one performed for the DCGLs should be provided.

   b) The dose assessment for SU22 only includes the dose from the survey unit average and Elevated Area (EA) #3. The dose from the other elevated areas in this survey unit should also be included in this dose assessment.

   c) Mallinckrodt should provide justification for the area and thickness of the elevated areas identified in SU22 (1a, 1b, 2, and 3).

      i. For EA#1, Figure 28-12 shows locations of samples and the delineated elevated area. However, samples 0333 and 0337 both have significantly elevated concentrations [sum of fractions (SOF) 22 and 7, respectively] but the delineated elevated area does not encompass these samples. Data from the samples 0333 and 0337 have not been included in estimating the Index values in Section 28.3.1.1. Thus, there does not appear to be clear rationale for the delineation of EA#1A and EA#1B as shown and the area of contamination.

      ii. For EA#2 and EA#3, Figure 28-11 shows the delineated elevated areas, but does not show the sampling and boring locations that were used to justify the delineation.

It also appears that there were not biased borings inside building 240 along the side of the building. Thus, there does not appear to be clear justification for the delineation of EA#2 and EA#3 and the area of contamination.

iii. Section 28.3.1 includes description of the size of the elevated areas, but the bases for the sizes are not provided. In particular, basis for determining that contamination does not extend laterally beyond the delineated areas has not been provided.

iv. Regarding the thickness of the contamination, the dose modeling in Section 28.5 indicates a thickness of 0.3 m, based on Section 28.5.2.1. However, Section 28.5.2.1 simply states that contamination was limited to approximately the top 1 ft of soil under the building foundation. This statement is not supported.

d) Mallinckrodt should provide justification that radionuclide concentrations used in the dose modeling for the elevated areas are representative or conservative. It appears the current concentrations used are based on a very small number of samples.

e) The total time in the trench assumed for the excavation scenario (0.5 hours per year) is not justified. If the worker were to spend more time in the trench, the dose would be higher than the dose that was calculated. The dose from the excavation scenario may be bounded by the dose from the *in situ* model since the worker in the *in situ* model spends more time on site. Either provide justification for the time assumed in the excavation scenario or provide a justification for how the dose from the excavation scenario is bounded by the dose from the *in situ* model.