

January 16, 2015

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

SUBJECT: RESPONSE TO OCTOBER 20, 2014, LETTER FROM MALLINCKRODT  
REGARDING THE JUSTIFIED CHANGE TO COLUMBIUM-TANTALUM (C-T)  
PHASE II DECOMMISSIONING PLAN EVALUATION

Dear Ms. Burke:

On October 20, 2014, Mallinckrodt provided the U.S. Nuclear Regulatory Commission (NRC) with the "Justified Change to ColumbiuM Tantalum (C-T) Phase II Decommissioning Plan Evaluation" (Agencywide Document Access and Management System [ADAMs] Accession No. ML14328A618). This document, described the evaluation Mallinckrodt performed to determine whether Mallinckrodt's proposed change in methodology to demonstrate compliance with the 25 mrem/yr unrestricted release criterion in 10 CFR 20.1402 required a license amendment. Mallinckrodt's proposed change in methodology involves using the dose assessment approach instead of the Derived Concentration Guideline Level (DCGL) approach to demonstrate that the dose limit is met. The DCGL approach was proposed by Mallinckrodt in the C-T Phase II Decommissioning Plan (DP) and was approved by the NRC in Amendment 5 to license STB-401 (ADAMs Accession No. ML091960063).

Section 9.5 of the C-T Phase II DP provides a list of conditions that must be satisfied for a change to be acceptable without a license amendment. In its evaluation, Mallinckrodt concluded that all of these conditions either were not applicable or were met.

The NRC staff has reviewed this evaluation and has concluded that while a dose assessment approach may be a valid approach for demonstrating compliance with the NRC's requirements, Mallinckrodt needs a license amendment prior to implementing this approach as some of the conditions for making this change without a license amendment were not met.

NRC finds that Mallinckrodt's justification associated with Condition D is inappropriate. Specifically, Condition D requires that the change be "consistent with the conclusions of actions analyzed in the Environmental Assessment." In its evaluation, Mallinckrodt did not address whether the change in methodology was consistent with the Environmental Assessment as required by the condition.

Additionally, Condition G in Section 9.5 of the Phase II DP requires that in order for a change to be made without a license amendment "the derived concentration guideline levels and related minimum detectable concentrations (for both scan and fixed measurement methods) will not be

increased.” In Mallinckrodt’s evaluation, it was concluded that this condition is not applicable because the change is an alternate major approach to the use of DCGLs. However, the NRC staff does not agree with this assessment. The use of the dose assessment approach potentially allows for higher levels of residual contamination to remain than would be allowed using the conservative DCGL approach. In fact, small areas of residual contamination that exceed the  $DCGL_w$  and  $DCGL_{EMC}$  values approved in the DP are expected to remain on the Mallinckrodt site following license termination if the dose assessment approach is implemented. Therefore, the NRC staff finds that the use of the dose assessment approach instead of the DCGL approach is inconsistent with Condition G.

As a result of the above staff’s assessment, the NRC has concluded that the change in methodology from license termination based upon DCGLs to license termination based upon a dose assessment is inappropriate without a license amendment. Therefore, Mallinckrodt should submit a license amendment request if they wish to utilize the dose assessment methodology.

In accordance with 10 CFR 2.390 of the NRC’s “Agency Rules of Practice and Procedure,” 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 the project managers, Jack Hayes at 301-415-5928 or via email at [John.Hayes@nrc.gov](mailto:John.Hayes@nrc.gov) or Karen Pinkston at 301-415-3650 or [Karen.Pinkston@nrc.gov](mailto:Karen.Pinkston@nrc.gov).

Sincerely,

**/RA/**

Michael Norato, Ph.D., 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

increased.” In Mallinckrodt’s evaluation, it was concluded that this condition is not applicable because the change is an alternate major approach to the use of DCGLs. However, the NRC staff does not agree with this assessment. The use of the dose assessment approach potentially allows for higher levels of residual contamination to remain than would be allowed using the conservative DCGL approach. In fact, small areas of residual contamination that exceed the  $DCGL_w$  and  $DCGL_{EMC}$  values approved in the DP are expected to remain on the Mallinckrodt site following license termination if the dose assessment approach is implemented. Therefore, the NRC staff finds that the use of the dose assessment approach instead of the DCGL approach is inconsistent with Condition G.

As a result of the above staff’s assessment, the NRC has concluded that the change in methodology from license termination based upon DCGLs to license termination based upon a dose assessment is inappropriate without a license amendment. Therefore, Mallinckrodt should submit a license amendment request if they wish to utilize the dose assessment methodology.

In accordance with 10 CFR 2.390 of the NRC’s “Agency Rules of Practice and Procedure,” 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 the project managers, Jack Hayes at 301-415-5928 or via email at [John.Hayes@nrc.gov](mailto:John.Hayes@nrc.gov) or Karen Pinkston at 301-415-3650 or [Karen.Pinkston@nrc.gov](mailto:Karen.Pinkston@nrc.gov).

Sincerely,

/RA/

Michael Norato, Ph.D., 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

**DISTRIBUTION:**

RidsRgn3MailCenter      GBonano, R III      SGiebel      DSchmidt

**ML14346A422**

<b>OFFICE:</b>	NMSS	NMSS	NMSS	NMSS	OGC	NMSS
<b>NAME:</b>	KPinkston	JHayes	TMoon	MNorato	BJones	MNorato
<b>DATE:</b>	12/11/14	12/11/14	1/14/15	12/18/14	1/9/15	1/16/15

**OFFICIAL RECORD COPY**