

Designate as original per KEP



February 12, 2015

40-6563

U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Two White Flint North Building  
11545 Rockville Pike  
Washington, DC 20555  
Attn: Mr. John Hayes

**RE: License Amendment Request  
Use of Dose Assessment Methodology  
Mallinckrodt LLC License Number STB-401**

Dear Mr. Hayes:

This letter and attachment constitute a request for amendment to the above referenced license for the St. Louis, Missouri facility. This amendment request is necessitated as a result of the Nuclear Regulatory Commission's assessment of the Justified Change to Columbium-Tantalum Phase II Decommissioning Plan evaluation dated October 20, 2014 (ADAMS No. ML 14328A618).

All other conditions relating to the subject license remain unchanged at this time.

Please contact me at 314-654-5838 if you require additional information regarding this matter. Your prompt review and consideration of this license amendment request is appreciated.

Sincerely,

A handwritten signature in cursive script that reads 'Karen Burke'.

Karen Burke  
Radiation Safety Officer

Enc: License Amendment Request

Cc: Karen Pinkston (NRC)

NM5501

License Amendment Request  
Use of Dose Assessment Methodology  
Mallinckrodt LLC  
NRC License STB-401  
NRC Docket 40-06563

The approved Mallinckrodt Columbium-Tantalum (C-T) Phase II Decommissioning Plan (DP) contains Derived Concentration Guideline Levels (DCGLs) for demonstrating compliance with License Termination Criteria contained in 10 CFR 20.1402. Mallinckrodt is requesting a license amendment to allow the option to perform direct dose assessment of residual radioactivity in addition to using DCGLs to demonstrate compliance with the license termination criteria.

The license termination criteria contained in 10 CFR 20.1402 specifies in part that, *"A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a Total Effective Dose Equivalent (TEDE) to an average member of the critical group that does not exceed 25 mrem per year, including that from groundwater sources of drinking water, and that the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA)."*

U.S. Nuclear Regulatory Commission (NRC) guidance provided in NUREG-1757, Vol. 2, Section 2.5, states, "There is flexibility in the general approach to demonstrating compliance with Title 10, Code of Federal Regulations (CFR), Part 20, Subpart E." Two major approaches described in the NRC guidance include 1) development of derived concentration guideline levels (DCGLs) and performance of final status surveys, and; 2) dose modeling following characterization and remediation as necessary. NUREG-1757 notes that the two approaches are not mutually exclusive and that both are acceptable to demonstrate that the dose due to residual radioactivity is acceptable.

The first approach, DCGL development and performance of final status surveys, is described in Chapters 5 and 14 of the NRC-approved C-T Phase II Decommissioning Plan (DP).

The DCGLs derived in the approved DP were conservatively developed. For example, the DCGLs are developed without any credit being taken for cover. That is, the contaminated zone is assumed to begin at site grade. In actuality, with the exception of soils beneath buildings or supporting structural foundations, contaminated soils have been excised between 1 meter and 5 meters deep and the resultant excavations have been backfilled with non-contaminated soil.

Since the reasonably foreseeable future site utilization is industrial in nature and groundwater wells are not used to supply drinking water, the conceptual site model used in the DP correctly identifies principal exposure pathways as direct radiation, soil ingestion, and inhaled activity associated with re-suspended soils. Dose

resulting from all of these exposure pathways is mitigated significantly by the presence of cover material. Consequently the DCGL development without consideration of the effects of cover is excessively conservative when evaluating elevated areas at depth (i.e., those 30 cm or more below site grade).

With respect to certain locations typically beneath buildings or structural foundations, in which residual radioactivity exceeds the DCGLs of the approved DP, compliance with the 25 mrem/yr dose limit can be demonstrated via direct dose assessment of the residual radioactivity. The ALARA component of the license termination criteria is also satisfied by the extent of remediation conducted throughout the Plant 5 area. Remaining residual radioactivity is limited in area and is inaccessible for removal without extraordinary measures such as undermining building foundations and structures or installing sheet pilings for soil stability.

Two exposure scenarios are contemplated for evaluating these elevated areas. The first is one in which the industrial worker is assumed to work onsite 50 weeks per year and in which the residual radioactivity is covered with a layer of non contaminated cover (e.g., soil or asphalt) equivalent to the depth below site grade of the residual radioactivity in that elevated area. This assumption is consistent with the residual radioactivity at the Mallinckrodt Plant 5 area. In assessing this exposure scenario a wind erosion rate consistent with the guidance contained in the RESRAD User's Manual and the physical features of the industrial facility will be utilized.

The second scenario represents a plausible intrusion into the industrial site. Since the future site utilization is industrial in nature, construction of a house with basement is unrealistic. In this situation the anticipated intrusion is that associated with pipeline installation or foundation construction. As part of the direct dose assessment, the more conservative of the two industrial intrusion activities will be evaluated for dose to the intruder.

As a separate issue also related to use of direct dose assessment for evaluating compliance with the license termination rule, the approved DP provides for calculation of an Elevated Measurement Comparison Limit Screening Test (Equations 14.7 and 14.9) for assessing the acceptability of elevated areas. While not necessarily incorrect, this calculation differs from the assessment of elevated areas using the Unity Rule per MARSSIM guidance (MARSSIM Equation 8.2).

In the paragraph following Eqn. 8.2 MARSSIM states, "As an alternative to the unity rule, the dose or risk due to the actual residual radioactivity distribution can be calculated if there is an appropriate exposure pathway model available." We would perform direct dose assessment of elevated areas that relied on equation 14.7 or 14.9 of the approved DP for demonstrating compliance with the license termination criteria.

For the reasons above, Mallinckrodt is requesting a license amendment to NRC License STB-401 to allow for the option of performing direct dose assessment to

assess potential future exposures in addition to DCGLs and Final Status Survey for demonstrating the Mallinckrodt facility meets the license termination dose criterion of 10 CFR 20.1402.