February 1, 2016

David J. Lamb, Director
Hazardous Waste Program
Missouri Department of Natural Resources
P.O. Box 176
Jefferson City, MO 65102

SUBJECT: RESPONSE TO MISSOURI DEPARTMENT OF NATURAL RESOURCES COMMENTS REGARDING THE DECOMMISSIONING OF THE MALLINCKRODT SITE, ST. LOUIS, MISSOURI

Dear Mr. Lamb:

Thank you for providing the Missouri Department of Natural Resources' (MDNR's) comments on the decommissioning of the Mallinckrodt, LLC. (Mallinckrodt) site in St. Louis, Missouri, in your December 1, 2015 letter (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15271A065). MDNR's comments were provided in response to the Memorandum of Understanding (MOU) consultation letter the U.S. Nuclear Regulatory Commission (NRC) sent to the U.S. Environmental Protection Agency (EPA) on June 10, 2015 (ML15131A508). The NRC consulted with the EPA about the Mallinckrodt site because the average concentrations of Ra-226 reported in Mallinckrodt's Final Status Survey Report (FSSR) (ML14177A180) in a small number of survey units are slightly above the trigger values in Table 1 of the 2002 "Memorandum of Understanding between the NRC and the EPA on Consultation and Finality on Decommissioning and Decontamination of Contaminated Sites."

The MDNR previously provided comments to the NRC on the decommissioning of the Mallinckrodt site on March 6, 2009 (ML090790209) during the NRC's review of the Mallinckrodt Phase II Decommissioning Plan (DP). The NRC and the MDNR held a meeting to discuss the NRC's response to these comments on April 24, 2009 (ML091240192).

The NRC's responses to the MDNR's December 1, 2015 comments are included in the Enclosure.

Based on its review of the FSSR and associated documents, the NRC concluded that the post-remediation residual radioactivity levels from licensed operations at the site will not result in a dose to the public in excess of 25 mrem/yr and are as low as is reasonably achievable (ALARA), even if the residual radioactivity is excavated. Therefore, the site meets NRC's criteria for unrestricted release in Title 10 of the Code of Federal Regulations (CFR), Part 20.1402.

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 NRC's ADAMS. ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

If you have any questions regarding this letter or the NRC's regulatory position on the decommissioning of the Mallinckrodt site, please contact Karen Pinkston, the project manager, at (301) 415-3650 or Karen.Pinkston@nrc.gov.

Sincerely,

***/RA/***

John R. Tappert, Director
Division of Decommissioning, Uranium Recovery,
and Waste Programs
Office of Nuclear Material Safety
and Safeguards

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

Enclosures:
Response to MDNR Comments

cc: D. Stalcup, EPA
Mallinckrodt Distribution List

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**Response to Missouri Department of Natural Resources Questions and Comments on the Memorandum of Understanding Consultation on the Decommissioning of the Mallinckrodt Site, St. Louis, Missouri**

1. **Comment:** According to the text of the letter, the values of the remaining material at the Mallinckrodt site are considered releasable for a U.S. Nuclear Regulatory Commission (NRC) industrial scenario. What provision is there to ensure that the area remains industrial outside of the information provided by the licensee that industrial is the most likely land use in the foreseeable future? The department recommends that in order to maintain protectiveness at the site, some method of institutional controls, such as a deed restriction or land covenant be placed on the property. Therefore, in the event of a land use change after completion of the decommissioning plan, a mechanism would exist that would prompt a re-evaluation of the site for its new land use.

   **NRC Response:** NUREG-1757 Vol 2, Rev. 1 contains NRC guidance on the exposure scenarios used in the dose assessments to demonstrate compliance with the radiological criteria for unrestricted use in Title 10 of the Code of Federal Regulations (CFR), Part 20.1402. This guidance allows for licensees to base their compliance scenario on the reasonably foreseeable land use for the area without institutional controls. This site is being released for unrestricted release. Institutional controls are required for restricted release. The NRC guidance defines “reasonably foreseeable land use” as “land use scenarios that are likely within 100 years, considering advice from land use planners and stakeholders on land use plans and trends”. The Mallinckrodt site in St. Louis is located in an urban industrial area in St Louis, and Mallinckrodt has operated chemical manufacturing facilities on the site since 1867. Mallinckrodt intends to continue industrial use of the site, and the foreseeable future use of the site is continued industrial or commercial use. The NRC staff therefore concluded that it was acceptable for Mallinckrodt to use the industrial land use scenario in their dose assessments as their compliance scenario. As is described in more detail in the response to Comment 3, Mallinckrodt also evaluated the potential dose to a worker who excavates into residual radioactivity located at depth.

   The NRC staff also concluded that it was acceptable for Mallinckrodt to exclude the groundwater pathway from their dose assessment because the groundwater beneath the site is saline, of poor quality, and is not used as a source of drinking water. The Mallinckrodt site is also located near the Mississippi River, which provides a large volume of high-quality water, so it is not expected that the groundwater beneath the site would be used as a drinking water source in the future. In addition, there are no surface streams or lakes on-site, so the surface water pathway is also not present. Without the water dependent pathways, the projected doses from other scenarios, such as the residential scenario, are comparable to the industrial scenario.

Based on its review, the NRC staff concluded that the residual radioactivity levels at the site would not result in a dose to the public in excess of 25 mrem/yr, and are As Low As is Reasonably Achievable (ALARA). Because the site meets NRC's criteria for unrestricted use in 10 CFR 20.1402, the NRC will not require the implementation of institutional controls.

2. **Comment:** The remaining material at the Mallinckrodt site outside of the U.S. Army Corps of Engineers (USACE) designated Formerly Utilized Sites Remedial Action Program (FUSRAP) areas will not have any action taken under the FUSRAP Downtown Record of Decision. Any areas of contamination that remain on FUSRAP areas that are above FUSRAP clean up levels due to inaccessibility issues will be required to have Institutional Controls in place. The purpose and use of Institutional Controls is to prevent the disturbance of remaining material. Institutional Controls are developed for a FUSRAP site in multiple layers of protectiveness, and for example, may include, but are not limited to: deed restrictions; land covenants; soil management plans; advisories; and, land use restrictions. The department strongly recommends that the licensee use Institutional Controls to prevent disturbance or intrusion of the remaining material on areas outside of future FUSRAP Institutional Controls.

   **NRC Response:** As is discussed in more detail in the response to Comment 1, the NRC staff concluded that the residual radioactivity levels at the site would not result in a dose to the public in excess of 25 mrem/yr, even if the material is excavated, and are ALARA. Therefore, the site meets NRC's criteria for unrestricted release in 10 CFR 20.1402. Because the site meets NRC's criteria for unrestricted use in 10 CFR 20.1402, the NRC will not require the implementation of institutional controls.

3. **Comment:** In lieu of Institutional Controls, it is recommended that procedures be implemented to ensure that construction or utility workers do not disturb contaminated or potentially contaminated soils. These procedures should include provisions for managing or storing contaminated soils and decontaminating tools, equipment, and personnel.

   **NRC Response:** As part of its dose assessments, Mallinckrodt included an excavation scenario in which a worker is exposed to elevated residual activity located at depth while excavating for activities such as pipe installation or constructing new building footers. In this evaluation, the projected dose from the elevated areas that had the potential to cause the highest doses was calculated. The highest dose calculated by Mallinckrodt for the excavation scenario was 2.5 mrem/yr. The NRC staff therefore concluded that the dose to an individual would be less than the 25 mrem/yr criteria, even if construction or utility workers disturb contaminated or potentially contaminated soils.

4. **Comment:** It is noted that the clean-up values for FUSRAP are less than those for the NRC, thus creating a disparity in clean-up level requirements. While these values may be considered acceptable for an industrial scenario in their present form, their proximity to FUSRAP areas that are considered "Group 2" (Inaccessible Soils), may present negative impacts to risk assessments and Institutional Controls that may be required for FUSRAP. What, if any, recourse is available should a situation arise that impacts FUSRAP area protectiveness due to different NRC values on adjacent areas?

   **NRC Response:** Although the clean-up values for FUSRAP are less than those for the NRC, the levels of residual radioactivity are much less than the NRC's clean-up levels and are generally below the FUSRAP clean-up values as well, with the exception of a few survey units that have average Ra-226 concentrations that are slightly above the FUSRAP clean-up values.

   The dose from the radionuclides present at the Mallinckrodt site is primarily through the direct radiation pathway. It is therefore not expected that an individual would simultaneously receive a dose from more than one area at the site. The residual radioactivity in the Columbium-Tantalum (C-T) process area portions of the site therefore should not have an effect on the FUSRAP area protectiveness.

5. **Comment:** The remaining materials at the current values are being considered for unrestricted license release. It is unclear if this analysis is limited to the NRC license material at the Mallinckrodt site, or includes the naturally radioactive material encountered below the license area (deeper in the ground) in certain areas of the site. This deeper material was associated with Mallinckrodt's work with tin ore in the late 19$^{th}$ century. Was this material considered in the *In Situ* and excavation scenarios presented in the Final Status Survey Report (FSSR)? Does the unrestricted license release evaluation include this deeper material or was it limited to what was determined to be licensed material?

   **NRC Response:** The NRC radiological criteria for unrestricted use in 10 CFR 20.1402 states, "A site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background radiation results in a dose that does not exceed 25 mrem/year…". Any unlicensed material, such as the tin ore, containing levels of radioactivity above background is therefore considered in the NRC's evaluations and the evaluation was not limited to licensed material for the Plant 5 portion of Mallinckrodt's site (i.e., the portion of the site where licensed activities primarily occurred).

The exception to this is the unlicensed Manhattan Engineer District/Atomic Energy Commission (MED/AEC) material at the Mallinckrodt site. In its approval of Mallinckrodt's Phase II Decommissioning Plan, the NRC exempted the MED/AEC material from consideration in demonstrating compliance. The basis for granting the exemption was: (1) Mallinckrodt will meet 25 mrem/yr unrestricted release criteria for C-T process areas; and, (2) unlicensed MED/AEC material is being remediated to NRC unrestricted release standards of 25 mrem/yr by USACE. The dose from the residual radioactivity at the site is primarily from the direct radiation pathway, therefore the NRC concluded that an individual would not simultaneously receive a dose from both areas (the C-T process areas, and the MED/AEC areas). Therefore, if USACE and Mallinckrodt independently demonstrate that the MED/AEC and C-T process areas, respectively, meet the NRC's unrestricted release criteria, then the entire site should meet the NRC's unrestricted release criteria at completion of site decommissioning activities. The NRC staff therefore concluded that it is reasonable to terminate Mallinckrodt's license (STB-401) after Mallinckrodt completes decommissioning activities in the C-T process areas and demonstrates that the C-T process areas at the site meet NRC's unrestricted release criteria. This finding is based in part on USACE's commitment to remediation of the site under FUSRAP.

6. **Comment:** There are no figures or maps depicting where the areas discussed are in relation to FUSRAP materials. Please consider including figures or maps to aid the reader in understanding the locations of the survey units discussed.

   **NRC Response:** The NRC staff agrees with this comment and has included figures and maps of the survey units in its Safety Evaluation Report for Mallinckrodt's FSSR.

7. **Comment:** In the event of a utility support, which currently occurs more than once a month through all of FUSRAP, would the areas considered for unrestricted license release pose an unacceptable risk to workers engaged in intrusive digging to address water main or other utility operations?

   **NRC Response:** As is discussed in more detail in the response to Comment 3, Mallinckrodt evaluated the potential dose to a worker engaged in digging and found that the potential dose was much less than 25 mrem/yr. The NRC staff therefore concluded that these areas would not pose an unacceptable risk to workers engaged in intrusive digging to address water main or other utility operations.