

**U.S. NUCLEAR REGULATORY COMMISSION**  
**DOCKET NO. 40-6563**  
**ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT RELATED**  
**TO THE ISSUANCE OF AMENDMENT NO. 7 TO MATERIALS LICENSE NO. STB-401,**  
**MALLINCKRODT LLC**  
**ST. LOUIS, MISSOURI**

1. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is considering approval of a request from Mallinckrodt LLC to amend NRC Source Materials License No. STB-401 that was submitted to the NRC on February 12, 2015 (ADAMS Accession No. ML15063A404). If approved, this license amendment would allow Mallinckrodt the option to perform direct dose assessment of residual radioactivity in addition to using derived concentration guideline levels (DCGLs) to demonstrate compliance with the license termination criteria in 10 CFR 20.1402 at the Mallinckrodt site in St. Louis, Missouri. The license currently states that decommissioning of the Columbium-Tantalum (C-T) process area building slabs and foundations, paved surfaces, and all subsurface materials, shall be done in accordance with the Mallinckrodt C-T Decommissioning Project, C-T Phase II Decommissioning Plan (DP), Revision 2, submitted to NRC on October 14, 2008 (ADAMS Accession No. ML083150652), and revisions submitted on June 3, 2010 (ADAMS Accession No. ML101620140). This DP only included the use of the DCGL approach to demonstrate compliance with the license termination criteria. A Notice of Availability of an Environmental Assessment (EA) and the Finding of No Significant Impact was published for NRC's approval of the DP in the *Federal Register* on July 1, 2010 (75 FR 38148). The NRC approved the DP on July 1, 2010 (ADAMS Accession No. ML091960063).

In response to Mallinckrodt's February 12, 2015 request, the NRC published notice of the request and an opportunity to request a hearing, or to petition for intervention in the *Federal Register* on June 4, 2015 (80 FR 31927). The NRC received no requests for intervention or hearing.

2. Proposed Action

The proposed action is approval of a requested license amendment. Mallinckrodt LLC requests the option to perform direct dose assessment of residual radioactivity in addition to using DCGLs to demonstrate compliance with the license termination criteria in 10 CFR 20.1402 at the Mallinckrodt site in St. Louis, Missouri. The NRC guidance in NUREG-1757, Vol. 2, allows for the use of either the DCGL or dose assessment approach in demonstrating compliance with the license termination criteria. In its amendment request, Mallinckrodt proposed to evaluate two different scenarios in its dose assessment: an industrial worker who works on the site and an intruder into the subsurface material. In the first scenario, the residual radioactivity that is located at depth is assumed to be covered with non-contaminated material. In the second

scenario, the potential dose due to an intrusion into the material because of pipeline installation or foundation construction is evaluated.

### 3. Need for the Proposed Action

Mallinckrodt is not permitted to use the dose assessment approach without a license amendment authorizing that approach. During site remediation, Mallinckrodt identified areas of elevated contamination that are located at depth in inaccessible areas. The DCGL values developed in Mallinckrodt's DP were based on the conservative assumption that the residual radioactivity was located at the surface. The use of the dose assessment approach instead of the DCGL approach allows Mallinckrodt to evaluate the actual configuration of residual radioactivity in a more realistic manner and thus to avoid conservative remediation activities not needed to protect health and safety.

### 4. Alternative to the Proposed Action

The alternative to the proposed action is the no action alternative; denial of the requested license amendment. Without the requested license amendment, Mallinckrodt would need to use the DCGL values approved in the DP to demonstrate compliance with 10 CFR 20.1402 in order to terminate their license. The removal of the inaccessible residual radioactivity to levels that are below the previously approved DCGL values would require extraordinary measures such as undermining building foundations and structures or installing sheet pilings for soil stability where a realistic assessment of the potential dose from the residual radioactivity would not require such action.

### 5. Environmental Impacts of the Proposed Action

The proposed action is administrative and would have no direct environmental impacts, but it would authorize Mallinckrodt to adopt a dose assessment approach to demonstrate compliance with the license termination criteria in 10 CFR 20.1402. The EA for Mallinckrodt's Phase II DP described the potential environmental effects from the remediation of radiologically contaminated soil and pavement of the site.

The maximum total radiological dose from both the proposed action and the previously approved DCGL values will be less than the 25 mrem/yr criteria in 10 CFR 20.1402. However, the configuration of the residual radioactivity allowed to remain at the site would likely be different based on the dose assessment approach than would be allowed based on the previously approved DCGL values. The DCGL values resulted in a lower total allowed level of residual radioactivity, while the dose assessment approach will result in a higher allowed level located at depth, based upon a more realistic approach. The projected dose from residual radioactivity at the Mallinckrodt site is through the direct radiation, soil ingestion, and inhalation of dust pathways. The projected dose from the in situ residual radioactivity located at depth under clean cover at the Mallinckrodt site is therefore much smaller than the dose from comparable residual radioactivity located at the surface. Mallinckrodt's evaluation of the

potential dose due to an intrusion event demonstrates that the dose will remain less than 25 mrem/yr even if the material is uncovered. The difficulty of additional remediation of residual radioactivity located in inaccessible areas makes such remediation unreasonable, therefore the ALARA requirement in 10 CFR 20.1402 is met for the dose assessment approach despite the potential reduction in required remediation activities based upon more accurate dose measurements.

There are no cumulative effects from the proposed action and previously approved actions at the site because the total dose from residual radioactivity at the site will continue to be less than the 25 mrem/yr criteria and there will be no additional environmental impacts beyond those described in the EA associated with the Phase II DP.

#### 6. Environmental Impacts of the Alternative to the Proposed Action

The only alternative to the proposed action is the no action alternative; denial of the requested license amendment. If Mallinckrodt is not authorized to use the dose assessment approach to demonstrate compliance with 10 CFR 20.1402, then Mallinckrodt would have to remove the inaccessible residual radioactivity to levels that are below the previously approved DCGL values in order to terminate their license. The removal of this material would require extraordinary measures to remove without damaging the buildings that are over this material based upon conservative DCGL values inconsistent with the physical configuration of the residual radioactivity. The additional removal also creates a potential for radiological environmental impacts. Radiological environmental impacts that could result from such remediation activities include exposure, inhalation, and ingestion hazards to workers and the public. These hazards could occur during excavation and loading of radioactively contaminated material. Air quality and noise impacts could also result from these remediation activities. The potential impacts from any additional remediation activities are described in the EA generated for the DP.

#### 7. Agencies and Persons Consulted

NRC staff provided a draft of this EA to the State of Missouri for review, and the State of Missouri did not provide any comments. The NRC did not consult with either the U.S. Fish and Wildlife Service or the State Historic Preservation Office because the proposed action, approval of the requested license amendment, can only result in a reduction of previously considered impacts to these resource areas. In fact, the need for the proposed action is to allow Mallinckrodt to avoid previously authorized activities that would be required in the absence of the proposed action.

#### 8. Conclusion

Per NRC guidance in NUREG-1757, Vol. 2, the use of the dose assessment approach is an acceptable mechanism for demonstrating compliance with 10 CFR 20.1402.

The NRC staff has prepared this EA in support of the proposed action to amend NRC Source Materials License No. STB-401. On the basis of this EA, NRC has concluded that there are no significant environmental impacts and the license amendment does not warrant the preparation of an Environmental Impact Statement. Accordingly, it has been determined that a Finding of No Significant Impact is appropriate.

#### 9. Preparer

This EA was prepared by Karen Pinkston, NRC Systems Performance Analyst, Division of Waste Management and Environmental Protection.

#### 10. Sources Used

Mallinckrodt Chemical, Inc., Mallinckrodt C-T Decommissioning Project, C-T Phase II Decommissioning Plan, Revision 2, October 14, 2008.

Mallinckrodt Pharmaceuticals, License Amendment Request – Use of Dose Assessment Methodology, February 12, 2015.

U.S. Army Corps of Engineers, Feasibility Study for the St. Louis Downtown Site, April 1998.

U.S. Nuclear Regulatory Commission, NUREG-1757, Vol. 2, Rev. 1, “Consolidated Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria,” September 2006.

U.S. Nuclear Regulatory Commission, “Notice of Availability of Environmental Assessment and Finding of No Significant Impact Related to Approval of the Mallinckrodt C-T Phase 2 Decommissioning Plan, Mallinckrodt, Inc., St. Louis, MO”, July 1, 2010.