

**OFFICE OF NUCLEAR MATERIAL SAFETY
AND SAFEGUARDS
SAFETY EVALUATION REPORT
RELATED TO APPROVAL OF MALLINCKRODT LICENSE AMENDMENT REQUEST FOR
THE USE OF DOSE ASSESSMENT TO DEMONSTRATE COMPLIANCE WITH
10 CFR 20.1402
LICENSE NO. STB-401 DOCKET NO. 40-6563
MALLINCKRODT, LLC
ST. LOUIS, MISSOURI**

Background

Mallinckrodt, LLC (Mallinckrodt) submitted a request to the U.S. Nuclear Regulatory Commission (NRC) to amend NRC Source Materials License No. STB-401 on February 12, 2015 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML15063A404). An NRC administrative review, documented in a letter to Mallinckrodt dated April 9, 2015, found the license amendment application acceptable for docketing, and the NRC staff began its technical review (ADAMS Accession No. ML15093A112).

In this request, Mallinckrodt, LLC requests 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 the 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.

The residual radiation at the Mallinckrodt site includes the thorium series (Th-232 and progeny), the uranium series (U-238 and progeny), and the actinium series (U-235 and progeny). In the DP, DCGL values were developed by Mallinckrodt for these radionuclides for pavement and for soil. An industrial scenario was used to derive these DCGL values. In the development of the DCGLs for soil, the residual radioactivity was assumed to be located at the surface without any cover. The NRC staff reviewed and approved these DCGL values as part of its review of the DP (ADAMS Accession Nos. ML101670444 and ML091831289).

During site remediation, Mallinckrodt identified some areas of elevated contamination at depth in inaccessible areas. Although the DCGLs values in the DP were generated based on the assumption that the residual radioactivity was located at the surface, much of the actual residual radioactivity on the site is located at depth with non-contaminated soil located above it. Mallinckrodt proposes now to use the dose assessment approach, in addition to the DCGL approach, to demonstrate compliance with the license termination criteria because the dose assessment approach allows for a more realistic representation of the residual contamination and a more realistic dose estimate.

Regulatory Requirements

The radiological criteria for unrestricted use of a site in 10 CFR 20.1402 states that a site will be considered acceptable for unrestricted use if the residual radioactivity that is distinguishable from background results in a total effective dose equivalent (TEDE) to an average member of the critical group that does not exceed 25 mrem (0.25 mSv) per year, including that from groundwater sources or drinking water, and that the residual radioactivity has been reduced to levels that are as low as reasonably achievable (ALARA). NRC guidance in NUREG-1757 Vol. 2, Rev. 1 states that there is flexibility in the approach used to demonstrate compliance with the 10 CFR Part 20, Subpart E dose criteria. The two major approaches described in this guidance are the dose assessment approach and the DCGL approach.

Proposed Dose Assessment Approach

In its amendment request, Mallinckrodt proposed to evaluate two different scenarios in its dose assessment: (1) an industrial worker who works on the site; and (2) an intruder into the subsurface material. In the first scenario, a projected dose to an industrial worker who works on-site for 50 weeks a year is evaluated. In this 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.

NRC Evaluation

NRC guidance in NUREG-1757 Vol. 2, Rev. 1 allows for either the DCGL or dose assessment approach to be used in the demonstration of compliance with the license termination criteria in 10 CFR 20.1402 and the use of either approach is acceptable to the NRC staff. As discussed in this guidance, the use of the dose assessment approach is a more realistic measure of the potential dose from a site. The NRC staff finds that the use of the dose assessment approach instead of the DCGL-only approach is acceptable and it allows Mallinckrodt to evaluate the actual configuration of residual radioactivity in a more realistic manner.

The industrial worker scenario is the same scenario assumed for development of the DCGL values in the DP. The NRC staff concluded that this scenario was appropriate during its review of the DP (ADAMS Accession No. ML091831289). The potential dose to a worker from material that is located at depth is much less than the dose from material that is 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 projected dose from residual radioactivity at the Mallinckrodt site is through direct radiation, soil ingestion, and inhalation of dust pathways. Water dependent pathways (i.e., groundwater or surface water pathways) are not present at the site. Because the projected dose is through the direct radiation, soil ingestion, and inhalation of dust pathways, an individual is not expected to receive a dose from multiple survey units at the same time. Unlike sites with water dependent doses an individual would not receive a dose from multiple survey units because water transportation of residual radioactivity from one survey unit to another is not possible, and therefore the residual radioactivity concentration and dose in a survey unit will not increase over time due to natural processes. Because the dose for the different survey units is independent, the NRC staff finds that it is acceptable for Mallinckrodt to use both the DCGL and dose

assessment approaches in demonstrating compliance, provided that for a given survey unit either the DCGL approach is used or a total dose for the survey unit is generated.¹

Conclusion

The NRC staff has concluded that it is acceptable for Mallinckrodt to use the dose assessment approach to demonstrate compliance with the license termination criteria in 10 CFR 20.1402. Although 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, in both cases the maximum dose is 25 mrem/yr. 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. But such potential changes only reflect a more realistic assessment, potentially avoiding conservative remediation activities not needed to protect health and safety.

Mallinckrodt provided the NRC with dose assessments as part of their Final Status Survey Report (FSSR) (ADAMS Accession No. ML14177A180) and request for additional information (RAI) responses (ADAMS Accession Nos. ML14339A278 and ML15177A051). NRC staff will provide a technical evaluation of the details of these dose assessments in a separate Safety Evaluation Report (SER) for the FSS (Final Status Survey).

References

Mallinckrodt, Inc., Mallinckrodt C-T Decommissioning Project, C-T Phase II Decommissioning Plan, Revision 2, October 14, 2008. (ADAMS Accession No. ML083150652).

Mallinckrodt, Inc., Revisions to Phase 2 Decommissioning Plan, June 3, 2010. (ADAMS Accession No. ML101620140).

Mallinckrodt Pharmaceuticals, Phase II Final Status Survey Report Mallinckrodt Columbiu-Tantalum Plant, April 9, 2014. (ADAMS Accession No. ML14177A180).

Mallinckrodt Pharmaceuticals, Response to the Request for Additional Information on Final Status Survey Reports for the C-T Phase II Decommissioning Plan, Mallinckrodt C-T Plant, November 19, 2014. (ADAMS Accession No. ML14339A278).

Mallinckrodt Pharmaceuticals, Response to the Request for Additional Information on Final Status Survey Reports for the C-T Phase II Decommissioning Plan, Mallinckrodt C-T Plant, June 10, 2015. (ADAMS Accession No. ML15177A051).

Mallinckrodt Pharmaceuticals, License Amendment Request – Use of Dose Assessment Methodology, February 12, 2015. (ADAMS Accession No. ML15063A404).

U.S. Nuclear Regulatory Commission, NUREG-1757, Vol. 2, Rev. 1, Consolidated Decommissioning Guidance: Characterization, Survey, and Determination of Radiological Criteria, September 2006. (ADAMS Accession No. ML063000252).

¹ For sites at which an individual could receive a dose from more than one survey unit at a time, the total dose would need to be evaluated on a site-wide basis when using the dose assessment approach.

U.S. Nuclear Regulatory Commission, Review of Dose Modeling for the Mallinckrodt Phase II Decommissioning Plan, July 6, 2009. (ADAMS Accession No. ML091831289).

U.S. Nuclear Regulatory Commission, Safety Evaluation Report Related to Approval of Mallinckrodt, Inc.'s Phase 2 Decommissioning Plan, July 1, 2010. (ADAMS Accession No. ML091960063).

U.S. Nuclear Regulatory Commission, Acceptance Review for February 12, 2015, Request for Amendment to the Mallinckrodt License to Allow for the Use of the Dose Assessment Approach to Demonstrate Compliance with License Termination Criteria. (ADAMS Accession No. ML15093A112).