[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[Docket No. 40-6563; NRC-2015-0139]

Mallinckrodt, LLC.

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering amending the NRC's Source Materials License No. STB-401 to allow 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 at the Mallinckrodt site in St. Louis, Missouri. The NRC staff is issuing an environmental assessment (EA) and finding of no significant impact (FONSI) associated with the proposed action.

DATES: The EA and FONSI referenced in this document are available on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Please refer to Docket ID **NRC-2015-0139** when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID **NRC-2015-0139**. Address questions about NRC dockets to Carol Gallagher;

telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The ADAMS accession number for each document referenced (if that document is available in ADAMS) is provided the first time that a document is referenced.
- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Karen Pinkston, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-415-3650; e-mail: Karen.Pinkston@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction.

The NRC is considering issuance of an amendment to the NRC's Source Materials License No. STB-401, issued to Mallinckrodt, for operation of their facility located in St. Louis, Missouri. This amendment allows 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 at the Mallinckrodt site in St. Louis, Missouri. Consistent with part 51 of title 10 of the *Code of Federal Regulations* (10 CFR), the NRC performed an EA. Based on the results of the EA described below, the NRC will not prepare an environmental impact statement for the license amendment, and is issuing a FONSI.

The NRC received, by letter dated February 12, 2015 (ADAMS Accession No. ML15063A404), an application from Mallinckrodt LLC to amend the NRC's Source Materials License No. STB-401. The licensee 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 license currently states that the 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). A Notice of Availability of an EA and FONSI was published for the NRC's approval of the DP in the *Federal Register* on July 1, 2010 (75 FR 38148). The NRC approved this DP on July 1, 2010 (ADAMS Accession No. ML091960063). The DP only included the use of the DCGL approach to demonstrate compliance with the license termination criteria. The NRC's guidance in NUREG-1757, Vol. 2, allows for the use of either the DCGL or dose assessment approach in demonstrating compliance with 10 CFR 20.1402.

On June 4, 2015, the NRC published in the *Federal Register* (80 FR 31927), a Notice of Opportunity for Hearing on the February 12, 2015, Mallinckrodt license amendment request. No request for a hearing was received.

II. Environmental Assessment.

Description of the 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's 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.

The proposed action is in accordance with the licensee's application dated February 12, 2015 (ADAMS Accession No. ML15063A404).

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. 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.

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, reflecting the fact that not all contamination is at the surface, which is assumed in the DCGL values. 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 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 reduction in required remediation activities.

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.

Environmental Impacts of the Alternatives to the Proposed Action

The alternative to the proposed action is 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 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. The additional removal also creates a potential for radiological environmental impacts. Radiological environmental impacts that could result from 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 for the DP, specifically, Phase II remediation activities.

Alternative Use of Resources

The proposed action does not affect any resource implications discussed in previous environmental reviews.

Agencies and Persons Consulted

In accordance with its stated policy, on September 15, 2015, the staff consulted with the Missouri Department of Natural Resources regarding the environmental impact of the proposed action. No comments were received. 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.

III. Finding of No Significant Impact.

Consistent with 10 CFR 51.21, the NRC conducted the EA for the proposed action described in Section II of this document, the EA is publicly available in ADAMS under Accession No. ML15268A311). On the basis of the environmental assessment, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC will not prepare an environmental impact statement for the proposed action.

Dated at Rockville, Maryland, this 4th day of January 2016.

For the Nuclear Regulatory Commission.

Michael A. Norato, Ph.D., Branch Chief,
Materials Decommissioning Branch
Division of Decommissioning, Uranium Recovery,
and Waste Programs
Office of Nuclear Material Safety
and Safeguards.

[FR Doc. 2016-02131 Filed: 2/3/2016 8:45 am; Publication Date: 2/4/2016]