October 28, 2013

Mr. Dexter Evans Senior Director Manufacturing Mallinckrodt, LLC 2703 Wagner Place Maryland Heights, MO 63043

SUBJECT: NRC INSPECTION REPORT 03000001/2013002(DNMS) – MALLINCKRODT, INC.

Dear Mr. Evans:

On October 3, 2013, Nuclear Regulatory Commission (NRC) inspectors performed an inspection at your Maryland Heights, Missouri, facility. The purpose of the inspection was to observe and evaluate the biennial emergency response exercise. On October 3, 2013, the inspectors discussed the inspection findings with you and members of your staff during the onsite exit meeting.

The inspection was conducted to determine whether Mallinckrodt personnel could successfully implement the Contingency Plan for the Maryland Heights, Missouri, facility. The inspection consisted of observations of selected exercise activities and evaluation of exercise performance.

Areas observed and evaluated during the exercise included, in part, the licensee's preparation for and control of the exercise; emergency command, control, and assessment from the field and the Emergency Communications Center; Fire Department response; and staff accountability. The inspectors also observed and evaluated contamination control, use of protective equipment, personnel and area surveys, environmental monitoring, communication effectiveness, dose estimates to licensee personnel and members of the public, and self-critique of the exercise by licensee staff.

The exercise of the Contingency Plan adequately tested the licensee's capability to respond to a radiological accident. Licensee staff completed appropriate and timely emergency response actions in response to the accident. Command and control, hazard assessment, dose assessment, and communications were adequate. Licensee staff discussed several ways to improve the licensee's emergency response during the post-exercise critique. The inspector's findings were consistent with those identified by the licensee.

Based on the results of this emergency response exercise, the NRC determined that Mallinckrodt personnel successfully demonstrated their capability to implement the Contingency Plan for the Maryland Heights, Missouri, facility in response to a simulated radiological accident. D. Evans

In accordance with Title 10 of the *Code of Federal Regulations* 2.390 of the NRC's "Rules of Practice," a copy of this letter will be made available electronically for public inspection in the NRC's Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC's website at http://www.nrc.gov/reading-rm/adams.html.

Please feel free to contact Ken Lambert of my staff if you have any questions regarding this inspection. Mr. Lambert can be reached at (630) 829-9633.

Sincerely,

/**RA**/

Aaron T. McCraw, Chief Materials Inspection Branch

Docket No. 030-00001 License No. 24-04206-01

cc: Gary Bosgraaf, RSO

D. Evans

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cc: Gary Bosgraaf, RSO

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