



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

OCT 27 2015

Eric Berry
Vice President – Environmental Law
Mallinckrodt, LLC
675 McDonnell Blvd.
Hazelwood, MO 63042

Dear Mr. Berry:

Thank you for your letter dated September 21, 2015, informing us about the impending internal reorganization within Mallinckrodt plc, the parent company of Mallinckrodt, LLC. This matter was discussed with you and Mr. James Schuh of your staff and Mr. Bryan Parker of my staff by telephone on September 16, 2015. Based on the information provided during this conversation and your letter dated September 21, 2015, including consultation from our Regional Counsel, we have concluded that this business transaction will not result in a change of control of Mallinckrodt, LLC.

If our understanding of this matter is not correct or if the circumstances described in your September 16, 2015 letter change, please contact us as soon as possible so we may evaluate the new or revised information.

Your letter dated September 21, 2015, indicated that this transaction is planned to occur on or about January 22, 2016. Please notify us within 30 days, in writing, after the transaction has been finalized and include information to support other necessary changes such as a facility name change. With this information, we can issue an amendment to the affected NRC licenses to reflect the transaction, if necessary. Please contact Mr. Parker at 678-828-7050, or by e-mail at bryan.parker@nrc.gov if you have any questions regarding this letter.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Patricia J. Pelke". The signature is fluid and cursive, with a large initial "P" and "J".

Patricia J. Pelke, Chief
Materials Licensing Branch

License Nos.: 24-04206-01,
24-04206-02 and
24-04206-05MD
Docket Nos.: 030-00001,
030-38173 and
030-10801