

December 27, 2006

EA-06-280
NMED No. 060715

Dale Simpson, Site Director
Mallinckrodt, Inc.
2703 Wagner Place
Maryland Heights, MO 63043

SUBJECT: NOTICE OF VIOLATION [NRC SPECIAL INSPECTION REPORT
NO. 030-00001/06-02(DNMS)] MALLINCKRODT, INC.

Dear Mr. Simpson:

This refers to information provided by members of your staff to the U.S. Nuclear Regulatory Commission (NRC) on September 28, 2006, concerning an inadvertent release of radioactive liquid waste in excess of regulatory limits to the sanitary sewer from the Mallinckrodt, Inc., facility in Maryland Heights, Missouri, on September 28, 2006. The NRC conducted a special inspection at that facility on October 16 and 17, 2006. During the inspection, an apparent violation of 10 CFR 20.2003, "Disposal by Release into Sanitary Sewerage," was identified for the release of liquid radioactive waste to the sewer system in excess of the regulatory limit. Also identified during the inspection was an apparent violation associated with Condition 23.A of the NRC Materials License issued to Mallinckrodt. The apparent violation of License Condition 23.A concerned the failure of a Mallinckrodt employee to verify the position of certain valves and have the valve position independently verified prior to initiating a planned release of liquid radioactive waste to the sewer system. The inspection report was mailed to you on November 14, 2006.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations identified in the report by either attending a predecisional enforcement conference (PEC) or by providing a written response before we made our final enforcement decision. On December 13, 2006, your Radiation Safety Officer (RSO) provided a written response to the apparent violations.

Based on the information developed during the inspection and the information that you provided in the December 13, 2006, response to the inspection report, the NRC has determined that violations of NRC requirements occurred. These violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. In summary, on September 28, 2006, a waste management technician, employed by Mallinckrodt, was assigned to drain liquid radioactive waste tanks to the sanitary sewer. The technician failed to verify that Valve No. FS2 was in the closed position and failed to have the valve alignment independently verified before the technician began to transfer liquid radioactive waste to the sanitary sewer. At the time of the transfer, Valve No. FS2 for a high-level liquid radioactive waste tank was partially open and 4.014 curies of technetium-99m and 0.110 curies of molybdenum-99 (NRC-licensed materials) were inadvertently released to

the sanitary sewer. The total quantity of NRC-licensed material released to the sanitary sewer on September 28, 2006, when combined with radioactive materials previously released during the year totaled 4.209 curies of readily soluble radioactive material released to the sanitary sewer during Calendar Year 2006. The release of 4.209 curies of radioactive material to the sanitary sewer exceeded the 1 curie limit specified in 10 CFR 20.2003(a). Additionally, the technician's failure to verify the valve alignment and have the valve line-up independently verified by designated employees constitutes a violation of Mallinckrodt Standard Operating Procedure (SOP), "Radioactive Liquid Waste Sampling and Discharge to the Sanitary Sewer." This SOP is a procedure required by Condition 23.A of the NRC Materials License issued to Mallinckrodt, Inc. The release of radioactive liquid waste to the sanitary sewer in excess of the prescribed annual limit is a serious regulatory concern and the violations are categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$16,250 is considered for a Severity Level III problem. Because your facility has been the subject of escalated enforcement actions within the last 2 years,¹ the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. Credit was warranted for the *Identification* factor since you identified the violations and notified the NRC of the release event. Credit was also warranted for corrective actions consisting of: (1) notifying the local sewer district of the event to ensure that no workers were working in the vicinity of the sewer line; (2) notifying licensee staff that no discharge of radioactive material to the sewer system would take place until further notice; (3) installing a lockout device on the valve controlling discharge of radioactive materials to the sanitary sewer and limiting possession of the key for the lock to the RSO; (4) installing a pipe plug to prevent release of liquid radioactive waste to the sanitary sewer; (5) revising procedures to require the presence of a knowledgeable manager to observe the transfer of radioactive liquid waste, including independent verification of valve positions; (6) providing training to all site employees on the importance of following procedures; and (7) installing a temporary tank to store radioactive liquid waste that will be generated during the remainder of Calendar Year 2006.

Therefore, to encourage prompt identification and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III problem constitutes escalated enforcement action, that may subject you to increased inspection effort.

¹ A Severity Level III violation without civil penalty was issued to Mallinckrodt, Inc., on August 25, 2005, for the deliberate failure of a supervisor to conduct radiation contamination and ambient exposure rate surveys prior to servicing a molybdenum-99/technetium-99m generator on March 25, 2004, at the Mallinckrodt facility in Maryland Heights, Missouri (EA-05-105).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 030-00001/60-02 (DNMS) and the December 13, 2006, letter from the licensee. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure and your response, should you choose to respond, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

/RA/

James L. Caldwell
Regional Administrator

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

Enclosure: Notice of Violation

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in Inspection Report No. 030-00001/60-02 (DNMS) and the December 13, 2006, letter from the licensee. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure and your response, should you choose to respond, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Significant Enforcement Actions**.

Sincerely,

/RA/

James L. Caldwell
Regional Administrator

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

Enclosure: Notice of Violation

FILE NAME: G:\EICS\06-280 SLIII No Civil Penalty - Mallinckrodt.wpd

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OFFICIAL RECORD COPY

Letter from J. Caldwell to D. Simpson dated December 27, 2006

SUBJECT: NOTICE OF VIOLATION (NRC SPECIAL INSPECTION REPORT
NO. 030-00001/06-02) MALLINCKRODT, INC.

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NOTICE OF VIOLATION

Mallinckrodt, Inc.
Maryland Heights, Missouri

Docket No. 030-00001
License No. 24-04206-01
EA-06-280

During an NRC inspection conducted on October 16 and 17, 2006, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 10 CFR 20.2003(a) requires, in part, that a licensee may discharge licensed material into sanitary sewerage if the following conditions are satisfied: (1) the radioactive material is readily soluble in water; (2) the quantity of radioactive material released in one month divided by the average monthly volume of water released into the sewer dose not exceed the concentrations listed in Table 3 of Appendix B to 10 CFR Part 20; (3) if more than one radionuclide is released, the licensee shall divide the monthly average concentration release into the sewer by the concentration of that nuclide in Table 3 of Appendix B to 10 CFR Part 20 and the sum of the fractions for each radionuclide does not exceed unity; and (4) the total quantity of licensed and other radioactive material that the licensee releases into the sanitary sewerage system in a year does not exceed 5 curies of hydrogen-3, 1 curie of carbon-14, and 1 curie of all other radioactive materials combined.

Contrary to the above, from January 1 to September 28, 2006, the licensee released 4.209 curies of radioactive materials, excluding hydrogen-3 and carbon-14, into the sanitary sewerage system, a quantity of radioactive material in excess of 1 curie in a year. Specifically, the licensee released 4.014 curies of technetium-99m and 0.110 curies of molybdenum-99 (NRC-licensed materials) to the sanitary sewage system on September 28, 2006, and when combined with previous releases during 2006, a total of 4.209 curies of readily soluble radioactive materials combined was released to the sanitary sewerage system during the year.

- B. Condition 23.A of NRC License No. 24-04206-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures, including any enclosures, contained in the license application, dated February 28, 2001.

Section 11 of the license application, dated February 28, 2001, titled, "Waste Management," provides, in part, that the licensee develop and implement written waste disposal procedures for radioactive material that meet the requirements of the applicable section of Subpart K to 10 CFR Part 20, which includes Section 20.2003, "Disposal by Release into Sanitary Sewerage."

Section II.A of the licensee's Standard Operating Procedure, "Radioactive Liquid Waste Sampling and Discharge to the Sanitary Sewer," dated March 28, 2000, implements Section 11 of the February 28, 2001, license application and requires that several valves, including Valve No. FS2, be closed or checked closed and the valve line-up verified by the Waste Management Coordinator or a Senior Health Physicist prior to continuing with the next step in the procedure.

Contrary to the above, on September 28, 2006, the licensee failed to close or check that several valves, including Valve No. FS2, were closed and failed to have the Waste Management Coordinator or a Senior Health Physicist verify the valve line-up prior to continuing with the next step in the procedure. Specifically, on September 28, 2006, the licensee's waste operator failed to close or check that several valves, including Valve No. FS2, were closed and failed to have the valve line-up verified by the Waste Management Coordinator or a Senior Health Physicist prior to continuing with the next step in the procedure, discharging radioactive liquid waste into the sanitary sewerage system.

This is a Severity Level III problem (Supplements IV and VI).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to be taken to correct the violations and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 030-00001/06-02(DNMS) and a December 13, 2006, letter from the licensee. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-06-280," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator and the Enforcement Officer, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 27th day of December 2006.