

December 22, 2003

EA-03-089

Mr. Mark Puett
Manager, Environmental Affairs
Mallinckrodt Chemical, Inc.
Mallinckrodt & Second Streets
P.O. Box 5439
St. Louis, MO 63147

SUBJECT: RESPONSE TO DISPUTED NOTICE OF VIOLATION
(NRC INSPECTION NO. 04006563/2003-001(DNMS))

Dear Mr. Puett:

This refers to the Notice of Violation (Notice) sent to you on July 17, 2003, concerning a violation of your NRC license. The violation involved the willful failure to conduct a final status survey using an approved field instruction and final status survey procedure for Survey Unit 9101. The violation was based on information obtained during the onsite inspection completed on January 9, 2003, at the Mallinckrodt Chemical facility in St. Louis, Missouri.

By letter, dated August 19, 2003, you submitted your response to the July 17, 2003 Notice. In your response, you agreed that the violation occurred, and that the final status survey was performed prior to workers obtaining all required signatures for both the field instruction and survey procedure. However, you disagreed that the violation was willful. Your response indicated that Mallinckrodt took immediate corrective actions in accordance with quality assurance requirements upon learning of the violation, and never deliberately violated, falsified, or carelessly disregarded regulatory requirements. In addition, you stated that Mallinckrodt relied upon its contractors to act in accordance with the procedures, and assumed that all signatures would have been obtained as required by the procedures.

The NRC originally determined that the violation was willful, based on the actions of your decommissioning contractor's managers, not on the actions of Mallinckrodt's managers. However, the description in the July 17, 2003 Notice did not differentiate between the licensee's management and the licensee contractor's management. During the onsite portion of the inspection, the contractor's managers explained to the inspector that they knew the field instruction and survey procedure for Survey Unit 9101 were required to be approved prior to implementation. However, since any changes to the field instruction or survey procedure would have been minor, and in order to keep the decommissioning project on schedule, the managers did not see any harm in implementing the instruction and procedure prior to approval. The contractor's managers violated the requirement to have the field instruction and survey procedure approved prior to implementation when they authorized the work to begin without the proper approvals. Due to the circumstances involved and the licensee's corrective actions, the NRC has chosen not to cite the contractor for the violation, which was of minor safety significance.

Consequently, based on the information contained in your August 19, 2003, letter and our current evaluation of the information obtained during the inspection, the NRC has concluded that an adequate basis was provided for modifying the violation. The violation, which is referenced in the July 17, 2003 Notice, is considered a minor violation, and will not be cited. Therefore, this letter will serve to modify the record to indicate that a minor violation occurred due to the actions of your contractor's managers, not as a result of willful actions on the part of Mallinckrodt's managers.

The NRC expects licensees to maintain control of all licensed activities conducted under their license. The NRC will hold licensees responsible for the acts of its employees and contractors working under the license. In addition, the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG 1600, provides that a violation may be considered more significant than the underlying noncompliance if it includes indications of willfulness.

You are not required to respond to this letter. In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter 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>.

Sincerely,

/RA by G. E. Grant Acting for/

James L. Caldwell
Regional Administrator

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