



Healthcare

Mallinckrodt

December 13, 2006

U.S. Nuclear Regulatory Commission, Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

RE: NRC License 24-04206-01
Response to Apparent Violations in Inspection Report 030-00001/06-02; EA-06-280

Dear Sir or Madam:

Mallinckrodt Inc. (MI) is providing this letter to the NRC in response to the subject inspection report. In that inspection report the NRC identified two apparent violations of NRC requirements. Specifically, the report identified (1) a release of radioactive material to the sanitary sewer in excess of the annual regulatory limit and (2) failure to fully implement a sewer release procedure as required by condition 23 of NRC License No 24-04206-01.

On September 28th, 2006 a Waste Management Technician inadvertently released some of the contents of a higher-level radioactive liquid waste tank along with the contents of a lower-level radioactive liquid waste tank to the sanitary sewer system. The event resulted in the release of 4.116 curies of radioactive material to the sanitary sewer. Although the event did not meet any NRC reporting requirements, Mallinckrodt conservatively notified the NRC of the event within four hours of its occurrence.

The NRC conducted a special inspection on October 16 and 17, 2006 to follow-up on the sewer release. You provided Mallinckrodt with the results of that inspection via an inspection report dated November 14, 2006. In the paragraphs that follow Mallinckrodt will address each of the apparent violations identified in that inspection report.

Apparent Violation 1: The licensee released a total of 4.209 Ci of readily soluble radioactive material to the sanitary sewer system in 2006. This exceeds the regulatory limits found in 10 CFR 20.2003(a).

- (1) **Reason for the apparent violation:** The violation was the result of a self-identified one-time inadvertent release of radioactive material to the sanitary sewer. Prior to the release which occurred on September 28, 2006 Mallinckrodt had released only 93 mCi of activity to the sanitary sewer in 2006. Operator error led to a discharge of 4.116 Ci of activity on September 28, 2006.
- (2) **Corrective steps that have been taken and the results achieved:** Upon identifying the release Mallinckrodt immediately notified the St. Louis Metropolitan Sewer District (MSD) about the release. The MSD verified that there were no workers in the sewer lines during the normal transit time from the point of discharge to the sewage treatment plant. The RSO notified all pertinent staff that further discharges of radioactive material to the sanitary sewer were prohibited until further notice. A lock-out device was placed on the valve that controls discharge to the sanitary sewer and the key was transferred to the RSO. The discharge line was subsequently blanked-off eliminating the potential for discharge to sanitary sewer regardless of valve position. Mallinckrodt secured temporary storage facilities to provide adequate storage capacity to accommodate radioactive liquid waste generated for the remainder of 2006. Mallinckrodt has not made any additional releases of radioactive material to the sanitary sewer since the event on September 28, 2006.

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- (3) **Corrective Steps that will be taken to avoid further violations:** Mallinckrodt has modified the SOP covering discharges of radioactive material to the sanitary sewer. This revision includes the addition of a checklist to document independent verification of valve positioning prior to initiating a discharge to the sanitary sewer. The procedure revision also includes a requirement to document tank levels before, during and after a discharge event. This provides verification that only the intended tank is being discharged to the sanitary sewer. All site employees have received documented training on the importance of following procedures as written.
- (4) **Date when full compliance will be achieved:** Mallinckrodt has been in compliance since September 28, 2006. Mallinckrodt has not made any additional discharges of radioactive material to the sanitary sewer since that date.

Apparent Violation 2: The licensee failed to fully implement a sewer release procedure as required by Condition 23 of NRC License No. 24-04206-01.

- (1) **Reason for the apparent violation:** The violation was the result of a Waste Management Technician's failure to obtain independent verification of valve positions prior to making a discharge to the sanitary sewer. Although the written procedure included a requirement to obtain the independent verification, the employee had been instructed by a former Waste Management Coordinator that it was no longer necessary to obtain the independent verification.
- (2) **Corrective steps that have been taken and the results achieved:** Mallinckrodt provided and documented training for all site employees about the importance of following procedures as written and approved. Employees were instructed to notify their Supervisor if a procedure can not be followed as written. Supervisors have reviewed written procedures in their areas of responsibility to insure they can be followed as written.
- (3) **Corrective Steps that will be taken to avoid further violations:** Mallinckrodt will continue to emphasize the importance of following procedures as written and approved.
- (4) **Date when full compliance will be achieved:** Mallinckrodt has been in compliance since September 28, 2006.

Mallinckrodt remains fully committed to complying with all NRC regulatory requirements. We believe the corrective actions we have identified and implement will prevent recurrence of the apparent violations identified in this letter. If you have any questions related to this matter, please feel free to contact me at 314-654-7981.

Sincerely,

Andrea Shipp for James R. Schuh.

James R. Schuh, CHP
Radiation Safety Officer
Manager, Environmental, Health and Safety

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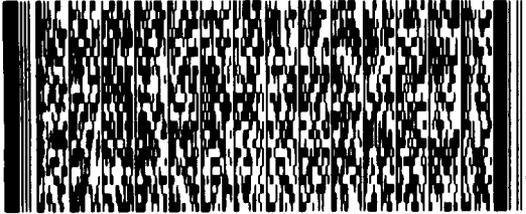
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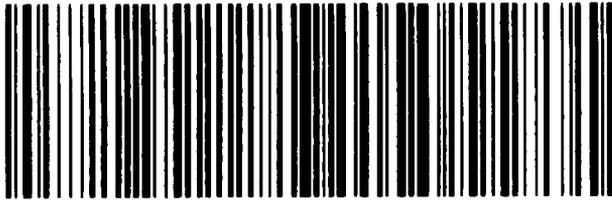
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