

NOTICE OF VIOLATION

Mallinckrodt Inc.
Maryland Heights, Missouri

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

During an NRC inspection conducted on the 22, 23, and 24th, of February 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

1. Condition 20. of License No. 24-04206-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated November 27, 1985, and letters dated December 12, 1986, January 5, 1987, October 20, 1987 and December 15, 1987.

Item 9.6 of the section of this application entitled, "Radioactive Protection In Manufacturing," states, in part, that the building 600 exhaust stack is equipped with a real time stack monitor capable of detecting accident level conditions for selected radionuclides. It further states that alarm points are built into the system to automatically shut down the radioactive effluent exhaust should these preset air concentrations be reached.

Contrary to the above, on approximately August 1, 1991, the real time monitoring system was rendered inoperative. Specifically, the link between the monitor and the computer in the Health Physics Office was disconnected.

This is a Severity Level IV violation (Supplement VI).

2. Condition 19. of License No. 24-04206-01 requires in part, that the licensee shall maintain, and execute the response measures of its Radiological Contingency Plan dated November 25, 1991. The condition also states that the licensee shall make no change in its Radiological Contingency Plan that would decrease the response effectiveness of the Plan without prior Commission approval as evidenced by license amendment.

Section 2.2.6. of Mallinckrodt Contingency Plan states that buildings 600 and 700 stacks are equipped with "real time" stack monitors designed to detect any abnormal releases and to provide a low and high level alarm due to radioactive discharges. The alarm condition is printed out on the printer located in the Health Physics office.

Contrary to the above, on approximately August 1, 1991, the real time monitoring system was rendered inoperative in that the link between the monitor and the computer in the Health Physics Office was disconnected. No prior Commission approval for this action was requested by the licensee.

This is a Severity Level IV violation (Supplement VI).

3. 10 CFR 71.5 requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.427 requires in part, that packaging which previously contained radioactive materials and has been emptied of contents as far as practical, is excepted from the shipping paper and certification, marking and labeling requirements of 49 CFR 173 if the packaging complies with the requirements of 49 CFR 173.421.

49 CFR 173.421 requires that the non-fixed (removable) radioactive surface contamination on the external surface of the package does not exceed the limits specified in 49 CFR 173.443(a).

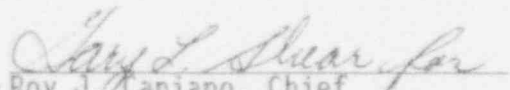
Contrary to the above, on six separate occasions during the period of time January 25 through February 19, 1993, the licensee shipped 15 and 30 gallon DOT Type A and B metal drums, marked "Empty" and failed to wipe test them to determine if the contamination levels exceeded the limits specified in 49 CFR 173.443(a).

This is a Severity Level IV violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, Mallinckrodt, Inc. is hereby required to submit a written statement of explanation to the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

MAR 22 1993

Dated _____


Roy J. Caniano, Chief
Nuclear Materials Safety Branch