

NOTICE OF VIOLATION

Mallinckrodt, Inc.
Maryland Heights, Missouri

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

During an NRC inspection conducted on January 9 to 12, 1996, with continuing review through January 29, 1996, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (60 FR 34381, dated June 30, 1995), the violation is listed below:

10 CFR 20.1906(b) and (c) require that each licensee monitor the external surfaces of a package labeled with a Radioactive White I, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4; and (2) radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to Part 71. This monitoring shall be performed as soon as practicable, but not later than 3 hours after receipt of the package during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Contrary to the above, as of January 12, 1996, the licensee received, on numerous occasions, packages labeled with a Radioactive White I, Yellow II, or Yellow III label during or after working hours, the packages were not exempt from the monitoring requirement for radioactive contamination levels, and the licensee did not perform the required monitoring. Specifically, the packages received by the licensee contained returned molybdenum-99/technetium-99 generators that were labeled and required monitoring.

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

Pursuant to the provisions of 10 CFR 2.201, Mallinckrodt, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to 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.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

Dated at Lisle, Illinois
this 9th day of February 1996