

APPENDIX A
NOTICE OF VIOLATION

Mallinckrodt, Inc.
Folcroft, Pennsylvania 19032

Docket No. 030-20537
License No. 37-21345-01MD

As a result of the inspection conducted on April 11, 1989, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1988), the following violation was identified:

Condition 23 of License No. 37-31245-01MD requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated April 8, 1983.

Item No. 10 of this application requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Regulatory Guide 10.8, Revision 4.

Section 2 of Appendix D, "Methods of Calibration of Dose Calibrators" requires instrument linearity to be tested at installation and quarterly thereafter.

Contrary to the above, dose calibrator linearity tests were not tested quarterly in 1988. Specifically, the dose calibrator was not tested for linearity in the first quarter of 1988 nor in the third quarter of 1988.

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

Pursuant to the provisions of 10 CFR 2.201, Mallinckrodt, Inc. is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including:

- (1) the corrective steps which have been taken and the results achieved;
- (2) corrective steps which will be taken to avoid further violations; and
- (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

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