

NOTICE OF VIOLATION

Mallinckrodt Medical, Inc.
Cleveland, Ohio

Docket No. 030-10703
License No. 34-16272-01

As a result of the inspection conducted on January 17, 1991, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (1990) (Enforcement Policy) the following violations were identified:

- a. 10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their plants or deliver 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 Part 170-189.

49 CFR 173.475(i) requires that, prior to each shipment of any package, the shipper ensure by examination or appropriate test that the external radiation and contamination levels are within allowable limits.

Contrary to the above, the inspector observed two packages containing limited quantity of radioactive material, and it was determined from a review of records and statements from licensee representatives, that the licensee has routinely transported the package since at least August 31, 1989, and has failed to perform tests to assure that the radiation and contamination levels were within allowable limits.

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

- b. 49 CFR 173.421-1(a) requires that licensees who ship or transport licensed material prepared under the provisions of 49 CFR 173.421 must include with the package a certification with the statement "This package conforms to the conditions and limitations specified in 49 CFR 173.421 for excepted radioactive material, limited quantity, N.O.S., UN 2910.

Contrary to the above, it was determined that the licensee has routinely transported packages of excepted radioactive material prepared under the provision of 49 CFR 173.421 and the licensee failed to include with each package the certification described above.

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

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Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each violation: (1) the corrective steps that have been taken and the results achieved; (2) the corrective steps that will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

FEB 1 1991

Dated _____

William H. Schultz
William H. Schultz, Chief
Nuclear Materials Safety
Section 1