

June 2, 1997
EN 97-044

OFFICE OF ENFORCEMENT
NOTIFICATION & SIGNIFICANT ENFORCEMENT ACTION

Licensee: Mallinckrodt Medical, Inc. (EA 97-155)
Maryland Heights, MO
Docket No. 030-00001

Subject: PROPOSED IMPOSITION OF CIVIL PENALTY - \$13,750

This is to inform the Commission that a Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$13,750 was issued on May 30, 1997, to the Mallinckrodt Medical, Inc., Maryland Heights, Missouri. This action is based on one violation of NRC regulations involving shipment of a Mo-99/Tc-99m generator for medical use where the radiation level at the surface of the package exceeded 200 millirems.

Since the licensee had been subject to escalated enforcement action within the last 2 years, the staff considered whether credit was warranted for identification or corrective action. The licensee identified the problem and reported it to NRC, therefore, credit was warranted for identification. No credit was warranted for corrective action because, although the generator was to be returned for special analysis and further investigation to determine the root cause of the event, it entered the licensee's normal waste stream and was destroyed, making a root cause determination impossible.

The State of Missouri will be notified.

The licensee has thirty days from the date of the Notice in which to respond. Following NRC evaluation of the response, the civil penalty may be remitted, mitigated, or imposed by Order.

Contacts: H. Clayton, RIII, 630-829-9666

M. Satorius, OE, 301-415-2747

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