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Region III Office of Public Affairs
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NRC STAFF PROPOSES \$13,750 FINE AGAINST
MALLINCKRODT MEDICAL, INC. FOR A SHIPPING VIOLATION

The Nuclear Regulatory Commission staff has proposed a \$13,750 fine against Mallinckrodt Medical, Inc., Maryland Heights, Missouri, for a shipment of radioactive pharmaceuticals which exceeded federal transportation limits on radiation levels.

On December 31 of last year, Mallinckrodt shipped a generator from its manufacturing plant in Maryland Heights, Missouri, to its nuclear pharmacy in Saginaw, Michigan. The generator produces radioactive technetium-99m that is used in medical diagnostic procedures. Upon arrival, the package containing the generator was surveyed and radiation levels on the surface were found to be 210 millirem per hour, exceeding the U.S. Department of Transportation limit of 200 millirem/hour.

(For comparison, the average person in the United States receives about 300 millirems per year from natural background radiation.)

NRC inspectors during a January inspection at the plant, noted that on the day the generator package was shipped to the pharmacy, surveys indicated radiation levels of 27 millirem per hour on the surface. There was no damage to the generator or to the package during the shipment and the pharmacy used the generator successfully.

Following the NRC inspection, Mallinckrodt instituted a program for more extensive surveys of outgoing packaged generators.

In a letter to the company, NRC's Regional Administrator, A. Bill Beach said:

"Based on your staff's discussion of the violation at the [April 30] predecisional enforcement conference, no root cause was determined and the various scenarios explored in an attempt to arrive at a cause were inconclusive. The potential safety significance associated with the licensed material involved and the inability to determine a root cause are of significant concern to the NRC."

Mallinckrodt has until June 29 to pay the fine or to protest it. If the fine is protested and subsequently imposed by the NRC staff, the company may request a hearing.

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