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NRC STAFF PROPOSES \$55,000 FINE AGAINST MALLINCKRODT
MEDICAL, INC. FOR RADIATION SAFETY VIOLATIONS

The Nuclear Regulatory Commission staff has proposed a \$55,000 fine against Mallinckrodt Medical, Inc., Maryland Heights, Missouri, for three radiation safety violations involving an employee radiation overexposure and two shipping incidents.

On May 14 of this year during routine clean-up of radioactive rhenium-186 waste and contaminated glassware, an employee received an exposure in excess of 290 rems to his thumb. (NRC's annual exposure limit to the hand of an occupational worker is 50 rems.) The radionuclide rhenium-186 is used by Mallinckrodt to conduct research. The contamination occurred either when the employee was cleaning up the waste material or when he removed his gloves.

Upon exiting the laboratory at the completion of his work, the employee performed a personal radiation survey. He was unable to get an accurate dose reading because of radiation emitted from some nearby radioactive material. The employee did not attempt to conduct another survey, and left the building for the evening.

The next morning, Mallinckrodt informed him that his routine urine sample from the previous evening showed levels of radioactivity that exceeded the company's limits. The company's internal limit is a small fraction of the regulatory limit. A subsequent radiation survey identified the contaminated thumb. The contaminated material was successfully removed.

The company also surveyed the building, the employee's residence and vehicle, and other places visited by the employee after he left work. Some items, including toweling and clothing, that were found to be contaminated at his residence were taken by Mallinckrodt for decontamination.

In notifying Mallinckrodt of the proposed fine NRC Regional Administrator A. Bill Beach stated, "The chain of events that allowed the contamination event to occur and then go undetected indicates that the controls and procedures that Mallinckrodt established were insufficient."

Immediately following the incident, NRC staff conducted a special

inspection at Mallinckrodt, performed independent surveys, and contracted with a medical consultant to review the employee's radiation exposure information. The consultant concluded that no immediate health effects would be expected.

Mallinckrodt instituted corrective actions following the event which included making radiation monitoring equipment more accessible to laboratory personnel.

A \$27,500 fine has been proposed for two violations associated with this May 14 incident: the actual employee overexposure and the failure to assure an adequate personal radiation survey was conducted prior to the employee leaving the building.

NRC staff proposed another \$27,500 fine for the shipment of two devices from its manufacturing plant in Missouri on July 8 of this year. Both packages exceeded the federal radiation limits for shipment of radioactive materials. The devices produce radioactive technetium-99m that is used in medical diagnostic procedures. The packages were shipped to Mallinckrodt's nuclear pharmacies in New Jersey and Pennsylvania with radiation levels on the outer surface of the packages of 250 millirem per hour and 240 millirem per hour, respectively. The federal limit is 200 millirem per hour

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

Mr. Beach noted in the letter that a \$13,750 fine was issued in May of this year for a similar generator shipping violation. As a result, the July 8 violations are repetitive and the normal fine was increased by 100 percent.

Mallinckrodt has until January 16 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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