



NRC NEWS

**U.S. NUCLEAR REGULATORY COMMISSION
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NRC ISSUES CONFIRMATORY ORDER TO MALLINCKRODT, INC., ON ACTIONS TO ADDRESS RADIATION OVEREXPOSURES TO WORKERS

The Nuclear Regulatory Commission staff has issued a confirmatory order to Mallinckrodt, Inc., of Maryland Heights, Missouri, requiring the company to review and improve its radiation protection program and its training for workers as a result of radiation overexposures to several employees in the past two years.

Mallinckrodt produces radioactive drugs that are used in research and in medical diagnosis and therapy. The company's processing and distribution of radioactive materials is regulated by the NRC and, for certain materials produced in a particle accelerator, by the State of Missouri.

On April 13 the company reported a radiation exposure above NRC limits to the hand of an employee. Subsequent reviews by the company and by a special NRC inspection team found several additional workers who had received radiation doses to their fingers and thumbs in excess of the NRC limit of 50 rems per year. Other employees have received radiation overexposures while handling state-regulated radioactive material.

The NRC Augmented Inspection Team, including four NRC inspectors and an inspector from the Missouri Department of Health, will discuss its findings with Mallinckrodt officials Friday (June 23). The meeting, which is open to public observation, will be at 9:30 a.m. in the Maryland Heights Community Center, Room 3, 2344 McKelvey Road, Maryland Heights.

Based on the team's findings, the NRC staff has concluded that there are deficiencies in the company's ability to evaluate the radiation safety aspects of its operations and to make accurate assessments of the causes of problems found. The agency is concerned that inadequate controls of the safe use of NRC-licensed materials continue to exist at Mallinckrodt's facility.

To address these deficiencies and concerns, the NRC is issuing the confirmatory order to document the company's agreement to:

1. Retain an independent organization to assess the radiation safety program and the radiation safety aspects of its radioactive material manufacturing processes.
2. Assure that its employees have received training in the procedures and practices to maintain radiation exposures as low as reasonably achievable.

3. Develop a plan to review its operations for the past five years to determine if any additional individuals have received radiation exposures above regulatory limits.

4. Develop a corrective action program with provisions for worker identification of radiation safety issues, notification to management of significant issues, and evaluation and tracking of those issues. This program will be incorporated into the company's NRC license.

The Confirmatory Order is available from the NRC Office of Public Affairs and will be posted on the agency's web site at: <<http://www.nrc.gov/OE/rpr/mat.htm>>.

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