



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION III  
801 WARRENVILLE ROAD  
LISLE, ILLINOIS 60532-4351

November 4, 1998

Les Sabo, Director  
U.S. Nuclear Medicine Operations  
Mallinckrodt, Inc.  
2703 Wagner Place  
Maryland Heights, MO 63043

SUBJECT: NRC INSPECTION REPORT 030-00001/98004(DNMS)  
AND NOTICE OF VIOLATION

Dear Mr. Sabo:

This refers to the inspection conducted on October 6, 1998, at Mallinckrodt, Inc., in Maryland Heights, Missouri, and Mallinckrodt Medical, Inc., in Hazelwood, Missouri, with NRC in-office review through October 16, 1998. The inspection evaluated the transportation incident that was reported to the NRC on September 28, 1998, by your customer who had received a package containing molybdenum-99 loading solution. During the NRC in-office review, the inspector evaluated your root cause analysis and corrective actions that included new and revised written standard operating procedures that we received on October 14, 1998. At the conclusion of the inspection on October 16, 1998, the inspector discussed the inspection findings with your Radiation Safety Officer, James R. Schuh.

Based on the information developed during the inspection, the NRC has determined that one Severity Level IV violation occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding the violation are described in detail in the subject inspection report. The violation involved failure to properly classify a package that contained hazardous material for shipment. This appeared to be an isolated breakdown of your process to notify individuals of the hazardous contents of your package.

While the package was not properly labeled, the NRC recognized that the packaging components were properly assembled as a certified, Type A package and the carrier handled the package consistent with the hazardous contents because the package accompanied other packages that were properly marked and labeled. There was no excessive radiation exposure to your workers, to the carrier and customer personnel or to members of the public. Finally, your root cause analysis properly identified inadequate work standards and inadequate training of your workers. Your corrective actions were prompt, comprehensive, and reasonable to prevent recurrence. As of the date of inspection, the workers were knowledgeable of the incident and the contributing factors and were implementing your corrective actions in their daily work practices. In addition, your managers were informed of the circumstances of the event and the corrective actions that involved new and revised written work standards that were subject to your approval process and that will be immediately communicated to the workers through your training programs.

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L. Sabo

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The NRC has concluded that the reasons for the violation and the corrective actions taken and/or planned to prevent recurrence have been adequately addressed. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosures, and your response, if you choose to provide one, will be placed in the NRC Public Document Room.

Sincerely,

/s/ G. C. Wright

Geoffrey C. Wright, Chief  
Materials Inspection Branch 2

Docket No. 030-00001  
License No. 24-04206-01

Enclosures: 1. Notice of Violation  
2. Inspection Report 030-00001/98004(DNMS)

cc w/encls: James R. Schuh, Radiation Safety Officer

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