



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, DC 20555 - 0001**

April 2, 2001

Joel Timberlake, Vice President  
Operations, Imaging Division  
Mallinckrodt, Inc.  
675 McDonnell Boulevard  
P.O. Box 5840  
St. Louis, MO 63134

**SUBJECT: CLOSURE OF JUNE 22, 2000 CONFIRMATORY ORDER MODIFYING  
LICENSE AND REPLY TO NOTICE OF VIOLATION AND PROPOSED  
IMPOSITION OF CIVIL PENALTY**

Dear Mr. Timberlake:

This acknowledges receipt of Mallinckrodt's letters dated June 28, 2000, July 6, 2000, September 20, 2000, and November 17, 2000, in response to the Confirmatory Order Modifying License issued on June 22, 2000. Each of these letters addressed the response requirements for specific sections of the Order. Based on our review of the information provided in these letters, we have concluded that the provisions of the Order have been met and we consider the Order closed. This also acknowledges Mallinckrodt's January 19, 2001, response to the December 21, 2000, Notice of Violation (Notice) and Mallinckrodt's payment of the proposed civil penalty. NRC will continue to examine Mallinckrodt's corrective actions during future inspections.

While Mallinckrodt did not contest the Notice, Mallinckrodt stated in its January 19, 2001, letter that it believes it was entitled to credit for identification of the violations contained in the Notice. The letter states that Mallinckrodt self-identified all of the overexposure events through internal investigations initiated in April 2000 and initiated corrective actions on its own.

Although we agree that Mallinckrodt identified that the overexposure events occurred, that fact was not sufficient to warrant identification credit. The NRC Enforcement Policy, contained in NUREG-1600, provides guidance for determining whether to give credit for identification in the civil penalty assessment process. This guidance is contained in Section VI.C.2.b. of the Policy, and states that credit is not appropriate in cases in which information available to the licensee should reasonably have caused action that would have prevented the violation. In Mallinckrodt's specific case, our inspections determined that you had information available to you regarding each exposure scenario, but did not recognize the significance of the information.

Specifically, with regard to the exposure involving handling of the molybdenum/technetium generator column, it was common knowledge among Mallinckrodt personnel in the generator manufacturing laboratory that rework involving removal of columns from their shields occurred during each manufacturing run. Although workers in the laboratory had been trained to perform the operation using remote handling tools, the fact remains that Mallinckrodt's procedures governing rework did not allow removal of columns from their shields. In addition, Mallinckrodt

logged three prior incidents in which rework staff exceeded their weekly administrative extremity exposure limits, but the investigations of those events were not of sufficient scope and detail to determine that the activities performed were not authorized. Those three incidents did not result in overexposures to the workers involved.

In the second instance, involving hand labeling of indium-111 product vials, Mallinckrodt designed and built a second packaging line, one purpose of which was to accommodate the remote labeling of the smaller vials. When Mallinckrodt was unable to make this line functional, you should have recognized that other provisions needed to be established for the labeling of the product vials to limit dose to laboratory workers.

In the third instance, involving the direct handling of sterility laboratory test samples, Mallinckrodt's health physics (HP) staff previously identified the poor practice, but failed to recognize its radiological significance. Even though the HP staff identified the potential source of dose, management only encouraged lab staff to use syringe shields and continued to allow the staff to directly handle sample vials.

We hope that this adequately addresses your questions regarding NRC's Enforcement Policy in general, and your specific concerns regarding our assessment of a civil penalty in your case. If you have any further questions regarding this matter, you may contact John Lubinski of my staff at (301) 415-2740.

Sincerely,

Frank J. Congel, Director  
Office of Enforcement

Docket No. 030-00001

cc: James Dyer, Regional Administrator

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