

June 13, 2005

EA-05-105
NMED Nos. 040331
030936

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

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03000001/2005-001(DNMS) AND
INVESTIGATION REPORT NO. 3-2004-024 - MALLINCKRODT, INC.

Dear Mr. Timberlake:

This refers to the inspection conducted from August 16 through 20, 2004, at the Mallinckrodt, Inc., Maryland Heights, Missouri, facility, with continued in-office review through May 19, 2005. The inspection included an investigation conducted by the Nuclear Regulatory Commission (NRC) Office of Investigations (OI), into an event involving a failure to conduct radiation surveys. This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. At the conclusion of the onsite inspection, the findings were discussed with you and other members of your staff. On May 19, and June 7, 2005, Robert Gattone, of my staff, discussed the inspection findings with Roland Sawyer, of your staff. The enclosed report presents the results of this inspection. The results of the investigation are documented in OI Report No. 3-2004-024, issued on March 23, 2005 (see Enclosure 1 for the OI Report Summary).

Based on the results of this inspection and our review of the OI report, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**. The apparent violation involved an individual's failure to conduct radiation surveys as required by Title 10 Code of Federal Regulations (CFR) Section 20.1501. As discussed with Mr. Sawyer on May 19, 2005, Mallinckrodt, Inc. is responsible for the acts and omissions of individuals who conduct activities authorized by Mallinckrodt, Inc.'s NRC license. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with Mr. Sawyer on May 19, 2005. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision.

In addition, since you identified the apparent violation and your facility has not been the subject of escalated enforcement actions within the last two years, and based on our understanding of your corrective action, a civil penalty may not be warranted in accordance with Section VI.C.2 of the Enforcement Policy. The final decision will be based on your confirming on the license docket that the corrective actions previously described to the staff have been or are being taken.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter or (2) request a predecisional enforcement conference. If a conference is held, it will be open for public observation. The NRC will also issue a press release to announce the conference. Please contact John Madera at 630-829-9834 within 7 days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to An Apparent Violation in Inspection Report No. 03000001/2005-001(DNMS); EA-05-105" and should include for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful." Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

Instead of a predecisional enforcement conference, you may request alternative dispute resolution (ADR) with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ during a pilot program which is now in effect is mediation. Additional information concerning the NRC's pilot program is described in the enclosed brochure (NUREG/BR-0317) and can be obtained at <http://www.nrc.gov/what-we-do/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR.

Based on the results of this inspection, the NRC has also determined that one Severity Level IV violation of NRC requirements occurred involving failure to maintain a record of the disposal of licensed material. This violation is being treated as a Non-Cited Violation (NCV), consistent with Section VI.A of the Enforcement Policy. The NCV is described in the subject inspection report. If you contest the violation or significance of the NCV, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to the Regional Administrator, Region III, and the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Enclosure 2 of this letter is exempt from public disclosure in accordance with 10 CFR 2.390, because its disclosure to unauthorized individuals could present a security vulnerability. Therefore, the material will not be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Because Enclosure 2 of this letter involves security-related information, your response, if you choose to provide one, will not be made available electronically for public inspection in the NRC Public Document Room or from ADAMS, accessible from the NRC Web site. Please mark your entire response "Exempt from Public Disclosure in Accordance with 10 CFR 2.390."

Sincerely,

/RA by G. Shear Acting for/
 Marc L. Dapas, Director
 Division of Nuclear Materials Safety

Docket No. 03000001
 License No. 24-04206-01

- Enclosures:
1. OI Report Summary
 2. Inspection Report 030-00001/2005-001(DNMS)(Exempt from Public Disclosure in Accordance with 10 CFR 2.390)
 3. Excerpt from NRC Information Notice 96-28
 4. NUREG/BR-0317, "Post-Investigation ADR Program"

cc w/encls: G. Diesl, Plant Manager
 R. Sawyer, Radiation Safety Officer

See Attached Distribution

ADAMS DOCUMENT TITLE: IR 03000001/05-001(DNMS) & Investigation Report No. 3-2004-024 - Mallinckrodt, Inc.

DOCUMENT NAME: E:\Filenet\ML051650548.wpd
 Publicly Available Non-Publicly Available Sensitive Non-Sensitive

To receive a copy of this document, indicate in the concurrence box "C" = Copy without attach/encl "E" = Copy with attach/encl "N" = No copy

OFFICE	RIII:DNMS	E	RIII:DNMS	E	RIII:DRP	E	RIII:DNMS	E
NAME	Gattone:mb		Parker by RGG for		Melendez-Colon by RGG for		Madera by RGG for	
DATE	05/27/05		05/27/05		05/27/05		05/27/05	
OFFICE	RIII:OI		RIII:EICS		RIII:DNMS			
NAME	Paul		O'Brien		Dapas by GLS for			
DATE	06/01/05		06/09/05		06/13/05			

Distribution:

Docket File w/encl

OE:EA File w/encl

M. Johnson, OE w/encl

C. Nolan, OE Section Chief w/encl

A. Hayes, OE Specialist w/encl

J. Moore, OGC w/encl

C. Miller, NMSS w/encl

G. Morell, NMSS w/encl

Enforcement Coordinator, RI w/encl

Enforcement Coordinator, RII w/encl

Enforcement Coordinator, RIII w/encl

Enforcement Coordinator, RIV w/encl

G. E. Grant, RIII w/encl

M. L. Dapas, RIII w/encl

OEMAIL

OE:EA(2)

**SUMMARY OF
OFFICE OF INVESTIGATIONS REPORT NUMBER 3-2004-024**

The Nuclear Regulatory Commission (NRC) Office of Investigations Report No. 3-2004-024 involves a first line supervisor (supervisor) at Mallinckrodt, Inc.'s (licensee's) Maryland Heights, Missouri facility who failed to conduct radiation surveys prior to conducting work with licensed material.

The supervisor was aware that a licensee's standard operating procedure (SOP) and NRC regulations required performance of radiation surveys of the work area prior to conducting customer complaint investigations of defective molybdenum-99/technetium-99m generators (generators). Nonetheless, the supervisor assumed that a generator had undergone radioactive decay to the point of no longer being radioactive. Therefore, the supervisor did not perform the required radiation surveys prior to conducting customer complaint investigations of a defective generator. As a result, the supervisor and another individual became contaminated with licensed material.

The supervisor said she was aware that the licensee's SOP and NRC regulations required her to conduct radiation surveys before working on the generator. The supervisor had over 10 years of experience in the nuclear field. In addition, the supervisor was training another employee on the licensee's procedure for conducting customer complaint investigations of defective generators when she failed to conduct the required radiation surveys.