

August 25, 2005

EA-05-105
NMED Nos. 040331
030936

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

SUBJECT: NOTICE OF VIOLATION [INSPECTION REPORT NO. 03000001/2005-001
(DNMS) AND OFFICE OF INVESTIGATIONS REPORT NO. 3-2004-024]

Dear Mr. Timberlake:

This refers to the routine safety inspection conducted from August 16 to August 20, 2004, at your facility in Maryland Heights, Missouri, and an investigation by the U.S. Nuclear Regulatory Commission (NRC) Office of Investigations (OI). Both the inspection and investigation reviewed the circumstances concerning a supervisor's failure to conduct radiation contamination and ambient exposure rate surveys prior to servicing a molybdenum-99/technetium-99m generator, an apparent violation of 10 CFR 20.1501, "Surveys and Monitoring - General." From information developed during the investigation, OI concluded that the supervisor deliberately failed to conduct surveys, prior to servicing a generator, on March 25, 2004. A summary of the OI report and a copy of the inspection report were provided to you on June 13, 2005.

In a letter dated June 13, 2005, transmitting the inspection report and OI report summary, we provided you the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference, requesting alternate dispute resolution, or providing a written response before we made our final enforcement decision. On June 20, 2005, you declined the opportunity to meet with the NRC staff to discuss the apparent violation in a predecisional enforcement conference and you did not request alternate dispute resolution. On June 27 and July 18, 2005, you provided written responses to the apparent violation.

Based on the information developed during the inspection and the investigation and information that you provided in your June 27 and July 18, 2005, letters, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the inspection and investigation reports. In summary, a supervisor, while conducting training of another employee,

failed to perform radiation contamination and ambient exposure surveys of a molybdenum-99/technetium-99m generator prior to servicing the generator. The supervisor was aware that the licensee's procedures and the NRC's regulations required the supervisor to conduct the surveys; however, the supervisor chose not to conduct the surveys, in part, based on an incorrect assumption that the NRC-licensed material had decayed for a period of time greater than 30 days beyond the generator expiration date. At the time, the generator contained molybdenum-99 and technetium-99m. During the servicing activities, neither the supervisor nor the other employee wore protective clothing. As a result, the employees' hands were contaminated with small quantities of radioactive material. The highest dose received by either of the employees was a shallow dose equivalent of 428 millirem averaged over 10 square centimeters, a dose that was much less than the regulatory limits, but nonetheless, a dose that could have been easily prevented had regulatory and/or license requirements been implemented.

The supervisor's failure to conduct radiation surveys prior to servicing the generator caused Mallinckrodt to be in violation of 10 CFR 20.1501. This violation was considered to be deliberate in nature based on the supervisor's prior: (1) experience servicing molybdenum-99/technetium-99m generators; (2) training in radiation safety; and (3) knowledge that Mallinckrodt's procedures and the NRC's regulations required the conduct of radiation surveys prior to servicing the generator. Therefore, the violation is categorized in accordance with the NRC Enforcement Policy at Severity Level III. The actions of the supervisor also placed the supervisor in violation of the NRC regulation prohibiting deliberate misconduct, 10 CFR 30.10. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**.

In accordance with the Enforcement Policy, a base civil penalty in the amount of \$3,000 is considered for a Severity Level III violation occurring on March 25, 2004. Because this was a deliberate violation, the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.C.2 of the Enforcement Policy. While the violation was identified as the result of an event, the NRC determined that credit was warranted for the *Identification* adjustment factor because you immediately stopped work, investigated the matter, notified the NRC and immediately notified all other site employees of the incident. The NRC determined that credit was warranted for the *Corrective Action* adjustment factor for your corrective actions which included: (1) taking disciplinary action; (2) creating a radiation work permit for servicing generators and prohibiting the dismantling of the generator columns; (3) modifying your standard operating procedure to address the use of remote handling equipment, task-specific instructions regarding personal protective equipment, verification of generator expiration dates, and mandatory health physics coverage while performing the standard operating procedure; and (4) retraining your staff on these issues.

Therefore, to encourage prompt identification and comprehensive correction of violations, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III violation constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03000001/2005-001(DNMS) and your June 27 and July 18, 2005, letters. Therefore, you are not required to respond to this letter unless the description in your response 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 specified in the enclosed Notice.

If you disagree with this enforcement action, 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](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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure, will 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>. To the extent possible, your response, if you choose

to respond, should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. The NRC also includes significant enforcement actions on its Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Significant Enforcement Actions**.

Please contact John Madera, Chief, Materials Inspection Branch at telephone number (630) 829-9834 if you have any questions.

Sincerely,

/RA Geoffrey E. Grant for/

James L. Caldwell
Regional Administrator

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

Enclosure: Notice of Violation

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

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NAME	Morrell ¹		Duffy ¹		O'Brien		Grant for Caldwell	
DATE	08/22/05		08/22/05		08/25/05		08/25/05	

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¹Concurrence from HQ in 8/22/05 e-mail from S. Merchant, OE, to Ken O'Brien, RIII

NOTICE OF VIOLATION

Tyco Healthcare/Mallinckrodt, Inc.
Maryland Heights, MO, Facility

Docket No. 030-00001
License No. 24-04206-01
EA-05-105

During an NRC inspection conducted from August 16 to August 20, 2004, and an NRC investigation completed on March 23, 2005, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the magnitude and extent of radiation levels, concentrations or quantities of radioactive material, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Contrary to the above, on March 25, 2004, the licensee did not make surveys to evaluate the potential radiological hazards present and to assure compliance with 10 CFR 20.1201, which requires, in part, that the licensee control the annual occupational dose to individual adults to: (1) 5 rems (total effective dose equivalent); (2) 50 rems (sum of the deep-dose equivalent and committed dose equivalent to any individual organ or tissue other than the lens of the eye); and (3) 50 rems (shallow-dose equivalent to the skin or to any extremity). Specifically, a supervisor failed to conduct radiation contamination and ambient exposure rate surveys in the work area prior to servicing a molybdenum-99/technetium-99m generator.

This is a Severity Level III violation (Supplement IV).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03000001/2005-001(DNMS) and your June 27 and July 18, 2005, letters. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description in your response does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; EA-05-105," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555 with a copy to the Regional Administrator and the Enforcement Officer, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352, within 30 days of the date of the letter transmitting this Notice of Violation.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

If you choose to respond, your response will 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>. Therefore, to the extent possible, the response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated this 25th day of August 2005.