

**tyco**

**Healthcare**

**Mallinckrodt**

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July 18, 2005

U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Washington, D.C. 20555-0001

RE: Amended Response to an Apparent Violation in Inspection Report No.  
03000001/2005-001 (DNMS); EA-05-105  
License Number 24-04206-01  
Docket Number 030-00001

Dear Sir or Madam:

Mallinckrodt Inc. (MI) hereby submits an amended response to the Apparent Violation listed in Inspection Report 0300001/2005-001(DNMS) and Investigation Report No. 3-2004-024, dated June 13, 2005. That report identified one apparent violation of Nuclear Regulatory Commission requirements with potential escalated enforcement:

**The inspectors identified an apparent violation of Title 10 Code of Federal Regulations (CFR) Section 20.1501 regarding failure to conduct radiation surveys, and it resulted in personnel contamination . . . Title 10 Code of Federal Regulations (CFR) Section 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 of 10 CFR Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present . . . The failure to conduct pre-work area radiation surveys before investigating a malfunctioning generator is an apparent violation of 10 CFR Section 20.1501.**

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Mallinckrodt Inc. accepts the “apparent” violation, however in order to mitigate possible enforcement actions Mallinckrodt Inc. respectfully requests consideration of the following:

**1. Corrective actions which have been taken and the results achieved**

Upon report of the incident, the immediate actions were:

- Job shut-down
- Personnel surveys and decontamination
- Individuals restricted from access to radiological areas
- Immediate, site-wide notification made to all employees of the facts surrounding the incident and path forward
- Dose assessments, including TLDs sent for emergency processing
- Ceased processing of DTE customer complaints pending completion of incident investigation
- Commencement of a formal incident investigation

Corrective actions as a result of the investigation were as follows:

- The individual involved was terminated for violating site work procedures
- Special Radiation Work Permit (RWP) was written to require Health Physics support during this task.
- A complete review of the DTE Customer Compliant process (SOP 5-18) was conducted. This review identified that the safety precautions, listed on the first page of SOP 5-18, were already in place and did not require revision.
- A detailed review was conducted of training records and qualifications of personnel authorized to perform this function. The investigation concluded that training and qualification requirements were both current and appropriate for this task.
- Site-wide refresher training was conducted, including implementation of an exam with a requirement of an 80% passing percentage, in the following areas:
  - Prohibition on contact handling
  - Label recognition
  - Basic radiation worker practicesThese topics were previously included as part of routine monthly training, however the radiation protection staff determined a focused session was warranted to heighten employee awareness.
- Label recognition, specifically NFPA and DOT, was added to routine monthly training
- Prohibition on dismantling DTE generator columns

**2. The corrective steps which will be taken to avoid further violations**

All corrective actions identified in Section 2 are adequate to prevent reoccurrence and have been implemented.

**3. The date when full compliance will be achieved**

All corrective actions were completed by July 2, 2004 prior to the NRC inspection in August of 2004.

In summary, this incident was self-identified and appropriate immediate actions were taken to address the issue including health physics surveys and decontamination procedures, as necessary. An incident investigation was conducted immediately and corrective actions identified by this investigation were entered into the site's corrective action program and tracked to completion prior to the NRC inspection in August 2004. Mallinckrodt as licensee understands its obligations to provide a strong radiation safety program and had adopted appropriate procedures for this job task and had trained personnel to implement such procedures. Furthermore, Mallinckrodt quickly self-identified the employee's failure to perform procedures as trained; addressed immediate safety concerns; conducted an internal incident investigation and completed all corrective actions in a timely manner. All of these actions strongly mitigated any serious adverse consequence from this incident. Additionally, Mallinckrodt has not been subject to any escalated enforcement activities within the last 2 years. These facts support a conclusion of issuance of an "apparent" violation with no civil penalties assessed and subsequently no issuance of any press release.

Mallinckrodt requests the NRC take these points into account as review of this matter is finalized. Thank you in advance for considering our request. If you have any questions concerning this response please do not hesitate to contact me at (314) 654-7644.

Sincerely,



Roland E. Sawyer  
Radiation Safety Officer/Manager, EH&S  
Tyco Healthcare/Mallinckrodt  
Maryland Heights Facility