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Healthcare

Mallinckrodt

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June 27, 2005

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

RE: 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:

Attached is the letter as a response to an Apparent Violation in Inspection Report No. 03000001/2005-001 (DNMS); EA-05-105.

If there are any questions feel free to contact me at 314-654-7644

Sincerely,



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

JE07

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RE: 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 responds 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.

Mallinckrodt Inc. respectfully disagrees with that assessment of an “apparent” violation and contests the identified apparent violation based upon the following:

1. Basis for contesting the apparent violation

This incident was self-identified at the time of occurrence and was included in the site’s corrective action program. Immediate and long-term actions are described in Section 2 below. Mallinckrodt’s radiation protection program and associated standard operating procedures clearly require that the appropriate radiation surveys be conducted in the cited situation. In fact, Inspection Report 0300001/2005-001, Section 2.2.a, paragraph 3 states:

“The pre-work area surveys were intended to evaluate the extent of radiation levels, and the potential radiological hazards that could be present prior to conducting work. Assessing radiation levels prior to conducting the work allowed workers to ensure that protective measures were taken commensurate with the radiological risk so that radiation doses were below the regulatory limits in 10 CFR Part 20.”

The individual involved in this incident was trained in both the procedural and NRC requirements to conduct pre-job radiation surveys. The subsequent investigation supported this fact. Furthermore, this individual had followed the procedures in the past demonstrating an understanding of the requirements when conducting the same tasks.

The requirements for a radiation protection program, as listed in 10 CFR 20.1101, are in part:

(a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part.

(b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

Mallinckrodt’s position is that the requirements of Section 20.1101(a) and (b) have clearly been met by Mallinckrodt as licensee through the provisions of its radiation protection program and therefore the employee’s failure to conduct appropriate radiation surveys in this incident was a noncompliance with an established procedure, not a violation of 10 CFR 20.1501(a).

2. 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

3. 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.

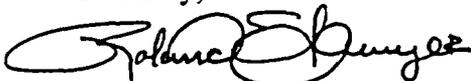
4. The date when full compliance will be achieved

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. Consequently, Mallinckrodt does not agree with the apparent violation of 10 CFR 20.1501(a) as stated in the letter dated June 13, 2005. 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 mitigate any serious adverse consequence from this incident and support a conclusion that an "apparent" violation potentially leading to escalated enforcement is not appropriate or warranted as there was no violation by licensee of 10 CFR 20.1501 (a).

Mallinckrodt urges the NRC to consider these points carefully as you review this matter. Thank you for your consideration of our position. 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
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