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June 30, 1997

Mallinckrodt Medical, Inc.  
2703 Wagner Place  
Maryland Heights, MO 63043  
Telephone (314) 770-7800

Mr. James Lieberman  
Director, Office of Enforcement  
U.S. Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike  
Rockville, MD 20852-2738

**Re: Reply to a Notice of Violation**  
**Docket No. 030-00001**  
**License No. 24-04206-01**

Dear Mr. Lieberman:

Mallinckrodt Inc., hereby replies to the NRC Notice of Violation, dated May 30, 1997, regarding the proposed imposition of civil penalty of \$13,750 (NRC Inspection Report No. 030-00001/97001(DNMS)) which was issued as a result of the incident on December 31, 1996, at the Mallinckrodt Inc., Nuclear Pharmacy in Saginaw, Michigan. The Saginaw incident involved a 12 Ci Ultra TechnaKow (UTK) generator which arrived with a radiation level of at least 200 mR/hr at the bottom of the package, from the Mallinckrodt Inc., Maryland Heights Missouri Facility

#### **Admission of Alleged Violation**

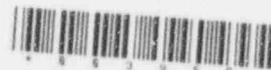
It appears that Mallinckrodt did violate radiation protection requirements specified in 10 CFR 71.5 (a) and 49 CFR 173.441 (a).

#### **Civil Penalty**

Mallinckrodt agrees that a civil penalty regarding these apparent violations is warranted. However, Mallinckrodt wishes to contest the level at which the NRC categorized the civil penalty related to the Saginaw incident. Based upon the amount of the civil penalty fee, it

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appears that the NRC had placed the Mallinckrodt Maryland Heights facility in the "b" category from Table 1A-Base Civil Penalties in the Civil Penalties section of Enforcement Actions, Federal Register, Volume 60 number 126, dated Friday, June 30, 1995. Mallinckrodt believes that the Maryland Heights Facility does not operate at the magnitude of risk implied by the examples of the "b" category. We believe that either the "c" or "d" category of referenced table is more appropriate for the nature of our operations. Therefore, we are requesting a re-evaluation and mitigation of the civil penalty. Also, Mallinckrodt requests clarification regarding the basis which the NRC used for categorizing the Maryland Heights Facility for the enforcement.

### **Reason for Violation**

Mallinckrodt recognizes the generator arrived at the Saginaw Nuclear Pharmacy with a package radiation level of 210 mR/hr. Mallinckrodt investigation results indicated that package radiation level survey information taken at the Saginaw Pharmacy, at the time of package receipt, was accurate.

### **Corrective Actions**

The corrective actions which have been taken as a direct result of the incident involve an enhanced package survey process prior to shipment from the Maryland Heights Facility. The results achieved by this enhanced process will assure that the radiation levels on the six sides of an outgoing generator package will be within expected levels. Mallinckrodt believes that this corrective action is proactive and may be pertinent to the cause of the incident. This corrective action expands surveillance which increases the likelihood of detecting possible problems with the generators.

The Dry Top Eluting (DTE) generator was developed to satisfy market indicators and to be proactive with FDA requirements. Radiation Protection enhancements were incorporated during the project development for the DTE generator. These enhancements augmented radiation protection of the laboratory technicians. The fundamental design of the DTE generator assisted with alleviating some of the unlikely adverse radiation protection scenarios associated with the transport of the UTK generators.

### **Items of Clarification**

#### *Misplacement of the Generator*

The misplacement of the generator was not a result of a miscommunication between the Radiation Safety Officer and Quality Control personnel. Instructions were given by the Radiation Safety Officer to the generator reclamation staff to store the generator for possible

additional testing and investigation. However, a few weeks later, it was inadvertently taken back out of storage by the reclamation department personnel and processed for reclamation. The most valuable investigative data was obtained during the investigation at the Saginaw Pharmacy, soon after the discovery of the incident. Since Mallinckrodt exhausted all possible investigation options during the investigation at the Saginaw Pharmacy, there were no tests planned for the return generator, at that time. It is important to realize that testing the returned generator after it experienced the rigors of a return shipment from the pharmacy back to the Maryland Heights Facility, may have introduced data unrelated to the cause of the incident.

#### *Wilkes-Barre*

Mallinckrodt wishes to clarify the footnote from page two of the NRC's letter dated May 30, 1997 that was attached with the Notice of Violation. The excessive radiation levels measured from the package received at the Wilkes-Barre Nuclear Pharmacy were a result of the incorrect back plate canister being assembled to the back of the generator and not because of the incorrect shielding on the back of the generator.

Mallinckrodt recognizes that the generator did arrive at the Saginaw Nuclear Pharmacy with package radiation levels at or slightly higher than 200 mR/hr. However, we wish to clarify that the June 10, 1995 Wilkes-Barre incident and subsequent corrective actions were unrelated to the Saginaw incident. Although there were no data which conclusively indicated the cause of the Saginaw incident, we confirmed during our investigation at the Saginaw Nuclear Pharmacy on January 3, 1997 that the generator was assembled properly.

#### **Closing**

Mallinckrodt is seriously concerned by the fact that a definite root cause of the Saginaw incident could not be determined. Mallinckrodt takes the requirements and responsibility to protect public health and safety very seriously.

Mallinckrodt provides both priority and significant amounts of resources to be proactive and maintain compliance with all the regulatory and license requirements for employee, environmental and public safety for a radiological safe environment and to prevent potential violations or situations that could cause violations of regulatory requirements.

Mallinckrodt requests that the NRC reevaluate the level at which the civil penalty was categorized. Please contact me at (314) 770-7940 or Daniel Riemer, Maryland Heights Radiation Safety Officer at (314) 770-7981 so we may discuss this matter and/or if you would like to arrange a meeting regarding this issue.

Sincerely,



Les Sabo  
Director of U.S. Nuclear Medicine Operations  
Mallinckrodt Inc.

cc: Mr. Roy Caniano  
Acting Deputy Director, Division of Nuclear Materials Safety  
U.S. Nuclear Regulatory Commission  
Region III

Mr. Monty Phillips  
Chief, Nuclear Materials Inspections, Section 2  
U.S. Nuclear Regulatory Commission  
Region III

Mr. Roy Brown  
Director of Regulatory Compliance  
Nuclear Medicine Division

Mr. Ron Bartnick  
Manager Quality/Regulatory Operations  
U.S. Nuclear Medicine Operations

Daniel Riemer  
Radiation Safety Officer  
Mallinckrodt Inc.,  
Maryland Heights, MO Facility