

May, 07 2003

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

RE: Reply to a Notice of Violation  
License Number 24-04206-01  
Docket Number 030-00001

Dear Sir or Madam:

Mallinckrodt Inc. (MI) hereby responds to the Notice of Violation (NOV) dated April 11, 2003. That NOV identified one violation of Nuclear Regulatory Commission requirements. In accordance with the Notice of Violation, Mallinckrodt Inc. responds below to the identified violation

A) 10 CFR 20.1601(a) requires, with exceptions not applicable here, that the licensee ensure that each entrance to a high radiation area has one or more of the following features: (1) a control device that, upon entry into the area, causes the level of radiation to be reduced below the level at which an individual might receive a deep-dose equivalent of 0.1 rem in one hour at 30 centimeters from the radiation source or from any surface that the radiation penetrates; (2) a control device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or (3) entryways that are locked, except during periods when access to the area is required, with positive control over each individual entry.

10 CFR 20.1601 (b) provides that, in place of the controls required by 10 CFR 20.1601(a) for a high radiation area, a licensee may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

Contrary to the above, as of June 5, 2002, the entrance to the Building 600 penthouse, a high radiation area with a radiation dose rate of approximately 500 mrem in one hour at 30 centimeters from the radiation source, was not controlled any of the methods described in 10 CFR 20.1601(a) or (b). Specifically the gate to a fenced-in, high radiation area in the penthouse of building 600 was identified with the closure yoke in locked position, yet the yoke was not engaged with the fence post. As a result, gate could be opened by unauthorized persons. In addition, as of June 5, 2002, the

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entrance to the building 600 mezzanine, a high radiation area with a dose rate in excess of 1000 mrem in one hour at 30 centimeters from the surface that the radiation penetrated, was not controlled by any of the methods described in 10 CFR 20.1601 (a) or (b). Specifically, the door (set of double doors) to a high radiation area in the mezzanine of Building 600 was identified propped open with a hand tool rendering it accessible to unauthorized persons.

#### **1. Reason for the violation**

This violation was a result of inadequate equipment to ensure compliant controls in accordance with 10CFR20.1602 were successfully implemented.

#### **2. Corrective Actions which Have Been Taken and the Results Achieved.**

The doors were immediately secured and restored to compliant condition.

A rapid report meeting with site personnel, where the EH&S manager discussed the violations as well as the importance and requirements of HRA control.

Additional meetings were held with HRA high use groups to reemphasize the control of subcontractors and their access to HRA's

The Health Physics group arranged for HRA door checks to be made on each work shift as a means of verifying compliance. Production team leaders implemented door checks in their areas of responsibility to increase the teams' accountability and identify hardware issues.

An investigation team was formed that identified the following steps to ensure improved compliance.

- Repair or replace inadequate hardware
- Install audible and/or visual alarms in remote locations
- Upgrade the new employee and contractor training program with regard to HRA control

### **3. The Corrective Steps Which Will Be Taken to Avoid Further Violations**

A capital project for HRA access control boundary relocation, hardware modifications and audible and visual alarms was completed in March 2003.

A dedicated section to the plant recurring training program now includes NRC regulations regarding misconduct by employees of a licensee.

The new employee and contractor training programs have been revised to include HRA training.

### **4. The Date When Full Compliance Will Be Achieved**

The facility is in full compliance.

If you have any questions concerning this response please feel free to contact me at (314) 654-7644.

Sincerely,

A handwritten signature in cursive script that reads "Roland E Sawyer". The signature is written in black ink and is positioned above the typed name.

Roland E Sawyer, RRPT / RSO  
Manager EH & S  
Tyco/Healthcare/Mallinckrodt  
Maryland Heights Facility