Dixie

MALLINCKRODT
Nuclear Medicine

March 2, 1994

Mallinckrodt Medical, Inc.
675 McDonnell Boulevard
PO Box 5840
St. Louis, MO 63134
Telephone (314) 895 2000

John A. Grobe, Chief
Nuclear Materials Inspection
Section 2
U.S. Nuclear Regulatory Commission
Region III
801 Warrensville Road
Lisle, Illinois 60532-4351

RE: Reply to a Notice of Violation
NRC License No. 24-04206-10MD
Docket No. 030-29675

Dear Mr. Grobe:

This letter is in reference to the Notice of Violation dated February 4, 1994 which resulted from an inspection at our Warren, Michigan pharmacy on December 22, 1993. Pursuant to the provisions of 10 CFR 2.201, Mallinckrodt Medical, Inc. is required to submit a written statement regarding the violations in the Notice.

Violation: Failure of the licensee to verify, prior to the transfer by an acceptable method, that the transferee's license authorized receipt of this material.

Response: As is the case with all of our clients, a letter was sent to Health Stop Medical Center several months prior to the expiration of their NRC license. The purpose of the letter was to remind the client of the pending expiration of their license and request a copy of the renewed license, a "deemed timely filed" letter or signed documentation that a renewal application has been submitted. Therefore, the reason for the violation was inadequate follow-up to the letter by facility personnel.

Health Stop Medical Center was contacted following the December 22, 1993 inspection to again request a copy of the renewed license or a "deemed timely filed" letter. A copy of Health Stop Medical Center's NRC license, expiration date June 30, 1998, is now on file.

To avoid further violations, the facility manager has implemented a more rigorous follow-up program once the initial request letter has been mailed. A copy of the letter is maintained on file with the client's licensing information. A current list is maintained by the facility manager as to when the letters went out and the results generated. If the client does not respond to the request in a timely manner,

the letter is followed by a phone call to request the necessary information.

Full compliance with this issuance was achieved as of January 1, 1994.

During our telephone conversation on February 3, 1993 and in your letter of February 4, 1993, you indicated your concern regarding the effectiveness of the Mallinckrodt Medical, Inc. internal audit program.

Following all internal audits, our pharmacy managers address items of non-compliance and devise corrective actions. They are to work with their regional manager to come up with methods that will correct the situation and prevent its reoccurrence. Their corrective actions are communicated to the corporate Operations Manager in the form of an NMA Audit Response which is sent within 30 days of receiving the internal audit report. Although this program has been successful throughout our pharmacy network, the incident which occurred in Warren, Michigan has demonstrated that some adjustments are necessary. The corrective actions determined by the Warren staff were appropriate for the incident which occurred, but the follow-up to insure the situation had been resolved was inadequate.

The NMA Audit Response program has been re-created in the form of a Mallinckrodt Medical, Inc. Diagnostic Imaging Services Standard Operating Procedure. The SOP outlines the reporting requirements for pharmacy managers when an item of non-compliance is found during an internal audit. The new SOP has been sent to all pharmacy and regional managers with a communication that details the incident which occurred in Warren. We used the violation as a teaching tool to demonstrate the consequences of not properly following up on corrective actions. The regional managers have been re-educated as to their role in helping to identify root causes of non-compliant items and using this information to assist in the development of appropriate corrective actions. Once corrective actions have been determined, the regional managers are required to follow-up with the pharmacy manager to insure proper implementation. The corporate Operations Manager will monitor implementation of corrective actions and appropriate follow-up by reviewing the NMA Audit Responses, regional manager monthly reports, and discussions with pharmacy and regional managers.

We hope that the information provided above has adequately addressed the violation identified during the December 22, 1993 NRC inspection as well as your concerns regarding our internal audit program. If you have any questions about the information discussed in this letter, please do not hesitate to call me at (314) 895-2388.

Sincerely,

Dennis M. Davis, RPh.
Operations Manager, DIS

cc: Warren Fadling
Mike Grawburg
Mike Whyte
Dave Weimer