



September 16, 1992

Ms. Jenny M. Johansen, Chief  
U.S. Nuclear Regulatory Commission  
Medical Licensing Section  
Region I  
475 Allendale Road  
King of Prussia, PA 19406

Mallinckrodt Medical, Inc.  
470 Frontage Road  
West Haven, CT 06516  
Telephone: 203 933 7064

RE: Response to a Notice of Violation (#030-30079/92-001)  
License Number: 06-28057-01MD

Dear Ms. Johansen:

Pursuant to the "Notice of Violation" dated August 26, 1992, the following response is provided:

As indicated, this licensee had performed a linearity evaluation on a repaired dose calibrator utilizing the Calicheck Kit and did not follow all of the manufacturer's instructions. Specifically, this licensee used the Calicheck Kit to perform an activity linearity evaluation on a repaired dose calibrator. The manufacturer's instructions require that linearity be established with standard techniques decay method prior to utilizing the Calicheck Kit.

In accordance with Item 10 E(3C) of the application, linearity testing shall be performed with the use of the Calicheck Kit from Cal Corporation Inc. The manufacturer's instruction for use dated March 2, 1982 will be followed. As stipulated in these instructions, activity linearity testing shall be performed utilizing standard techniques as described in the license application upon installation and/or repair. The Calicheck Kit will only be utilized for testing once activity linearity has been verified using standard methods and when new correction factors have been established for the Calicheck Kit.

This area of regulatory noncompliance was the result of an oversight by nuclearpharmacy personnel. Corrective action has been implemented in order to assure that this occurrence does not repeat itself. Educational updating and training has been provided to all nuclearpharmacy personnel performing activity linearity evaluations. These instructions have emphasized that license conditions and manufacturer's instructions will be followed when performing these procedures. Activity linearity testing procedures and record keeping practices will be monitored closely by the Radiation Safety Officer.

I trust that this response meets with your satisfaction. I thank you for your assistance and invite you to inspect our facility at your convenience.

Sincerely,

John P. Minella, R.Ph.  
Radiation Safety Officer & Facility Manager

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