The Du Pont Merck Pharmaceutical Company

Radiopharmaceutical Division 331 Treble Cove Road N. Billerica, MA 01862

(508) 667 9531

DUPONT MERCK 71-0384

April 7, 1994

United States Nuclear Regulatory Commission

Attn.: Thomas Matula

Division of Safeguards and Transportation, NMSS

Washington, D.C. 20555

Reference: Quality Assurance Program Approval No. 0384

Dear Mr. Matula.

This is written in response to observations and questions raised by yourself and Mr. O'Connor during your inspection of the Type B Container Quality Assurance Program at the DuPont Merck Pharmaceutical Company's site in North Billerica, MA on Wednesday March 30, 1994.

I am providing information on three observations discussed during the exit interview, in an attempt to help clarify the scope of activities conducted under our Type B Container Quality Assurance Program.

## 1. Applicability of 10 CFR Part 21

As discussed during the inspection, we are strictly a user of DOT Type B containers primarily for the receipt of radioactive raw material for our manufacturing operations. On occasion, once or twice yearly, we utilize a Type B container to facilitate shipments of radioactive waste off-site. As defined in the regulations of 10 CFR Part 21 §21.3, for these few Type B shipments the containers remain the property of the commercial radioactive broker we utilize and there are no procurement contracts that would specify what constitutes a defect. In addition, as you know we do not perform any maintenance or repairs to any of the Type B containers we handle.

Therefore, we are of the opinion that our Type B Quality Assurance Program does not require a procedure in conformance with the requirements of 10 CFR 21 §21.21. The notice to employees as required by 10 CFR 21 §21.6, is conspicuously posted on bulletin boards in each building on site in compliance with the requirements of our NRC broad scope materials license.

## 2. Calibration of torque wrench

The owner's specifications, as indicated in the container user's manual, for the Type B container in use require that bolts be torqued to 70 (+/-7) ft. lb. on the cask lid and 120 (+/- 12) ft. lb. on the overpack lid. Each of these torque specifications is within the 20% to 80% use range of the 0-250 ft. lb. torque wrench in current use for the Type B containers.

The torque wrench was sent off-site to an ISO certified and NIST traceable vendor for calibration on Monday April 4, 1994.

080042



