PACIFIC RADIOPHARMACY, LTD.
347 NORTH KUAKINI STREET * HONOLULU, HAWAII 96817
TELEPHONE (808) 547-9580

June 17, 1994

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

To Whom it May Concern:

RE: Reply to Notice of Violation/License #53-16991-01MD NCR Inspection Reports 030-12031/94-01 and 94-02

This is a written statement in response to the Notice of Violation correspondence dated May 20, 1994. As a result of inspection reports referenced above, we have acknowledged the need to provide additional training and supervision to the radiopharmacy staff. The Board of Directors of Pacific Radiopharmacy, Ltd., has made the commitment to become more actively involved in the management and oversight of the nuclear pharmacy procedures and general operations.

The Radiation Protection Officer (RPO) has reviewed the policies and procedures of the NRC Radioactive Materials License as well as the applicable NRC and DOT regulations related to shipment and release of radioactive materials with the pharmacy staff. Instruction has been provided on an individual basis to members of the staff as well as in conjunction with NMA Medical Physics Consultation. This consulting group was contracted January 12, 1994, and assists our organization with radiation safety and regulatory issues. Trent T. Phan, RPO, has instituted a program for periodic direct supervision of the driving staff during radiopharmaceutical deliveries. A new employee has been hired to answer the telephone and perform computer input in order to free up time for the Radiation Protection Officer to perform his duties. Richard Naito, R.Ph., will be added as an authorized user to the Radioactive Materials License. Mr. Naito will take an active role in the radiopharmacy's operation. This will be all performed under the Radiation Protection Officer's supervision.

Members of the Board of Directors of Pacific Radiopharmacy, Ltd., will attend a 24-hour regulatory review course through NMA Medical Physics Consultation on July 31, August 1 and 2, 1994. These members of the Board intend to be more directly involved in the pharmacy operations. This program should strengthen the knowledge and actions of all members of the radiopharmacy staff in order to maintain compliance with NRC and DOT regulations as well as license requirements. The Radiation Protection Officer has had more time to make a concentrated effort to manage the Radiation Protection Program.

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Each of the following responses are keyed to the items listed in the NRC Inspection Report dated May 20, 1994.

A. We acknowledge that the violation occurred on a number of occasions as stated in the Notice of Violation correspondence. We note the importance of transporting radiopharmaceutical products in DOT Type 7A cardboard boxes and metal containers as required. This violation occurred due to a lack of understanding by a staff member regarding the shipping and receiving policies and procedures of this radiopharmacy. Failure to follow the Radiation Protection Officer's instruction will result in employee disciplinary action in any future circumstances.

Steps were implemented as of February 17, 1994 when the Radiation Protection Officer again reminded the radiopharmacy staff that only the DOT Type 7A boxes and case for delivery of radioactive materials is acceptable. Effective April 15, 1994, all radioactive material deliveries are made utilizing DOT Type 7A cardboard boxes and the certified attache case. The delivery of radiopharmaceuticals to a number of the pharmacy customers was observed by an NMA consultant in May 1994. Recommendations were provided in order to improve the system.

Corrective steps to avoid future violations included a training session by NMA related to DOT and NRC regulations for receipt and transport of radioactive materials. This training session was held on May 22, 1994 for employees of the pharmacy and was under the direction of the Radiation Protection Officer. Periodic training sessions as well as supervision will be under the direction of the Radiation Protection Officer.

Consideration is being given to the purchase of either the DOT Type 7A attachè cases or AMMO boxes utilized by Mallinckrodt and Syncor nuclear pharmacies, respectively. It is anticipated that these cases of AMMO boxes will be in full use by September 1, 1994. These containers will be DOT Type 7A certified, as required.

B.1. We acknowledge that the violation relating to the omission of some of the DOT required radioactive material shipping information occurred as stated and recognize the importance of complying with these regulations. We have used the radiopharmacy computer program developed by the Nuclear Medicine Consulting firm (Greenville, PA) and were unaware of the missed information on the printout on this program. We admit that this was an oversight by the Radiation Protection Officer.

The corrective steps taken were to manually implement the shipping information required until the arrival of the Nuclear Medicine Consulting firm consultant on April 30, 1994. The consultant altered the computer program to include all required DOT shipping information. This correction includes all bar code information as well. Corrective steps for future violations were implemented as of March 8, 1994, by the manual entry of required information.

A program was started for RPO review of shipping papers in conjunction with another member of the staff prior to package shipment. As previously mentioned, a new member of the staff was hired to answer the telephone and assist with some of the paper work in order to provide more time in the mornings for the Radiation Protection Officer to supervise the shipping procedures. Compliance was achieved on May 2, 1994 when the computer system shipping papers were corrected to include all required information.

B.2. The Radiation Protection Officer was unaware of the requirement regarding the number of radiopharmaceutical vial containers allowed in the DOT Type 7A cardboard boxes utilized for radiopharmaceutical delivery. These containers were certified by Mallinckrodt for 2-can and 4-can usage. Dr. Phan contacted the supervisor of health physics services at the Mallinckrodt Medical, Inc. manufacturing plant to obtain information regarding the proper certification for the Mallinckrodt DOT 7A containers. A letter was sent to this radiopharmacy detailing the certification process for these containers. Dr. Phan performed the specification Type 7A tests to certify the boxes on May 7, 1994. Full compliance was achieved on that date. Any new containers will be properly certified prior to their use for transport of radioactive materials.

C. We acknowledge that the violation occurred as stated. We recognize the importance of performance of the AL+3 evaluation. The reason for the violation was a lack of knowledge on the full requirement for this aluminum ion check. Steps were taken to order a new kit on March 3, 1994, which was received on March 7, 1994. The Aluminum +3 evaluation is being performed as required beginning March 7, 1994 when full compliance was achieved.

D. We acknowledge the violation occurred as stated for the initial calibration check of the Victoreen Deluxe wipe test counter, Model #05-578, due to an oversight by the radiopharmacy. Steps were taken following discussion with the NRC inspector and the calibration was completed on April 9, 1994 in accordance with the counter's instruction manual. Compliance was achieved on April 9, 1994.

We have made every effort to correct the aforementioned items as advised by NRC inspectors. As previously mentioned, attention is being given to providing more supervision and training by Dr. Phan and the Board of Directors of the radiopharmacy. If you have further questions, please do not hesitate to contact me at (808) 547-4305 or Dr. Phan at (808) 547-9580.

Respectfully,

Calvin Ichinose
President

cc: Regional Administrator, NRC Region IV
Director, NRC Walnut Creek Field Office