APPENDIX A

NOTICE OF VIOLATION

Pacific Radiopharmacy, Ltd.
Honolulu, Hawaii

Docket No. 030-12031
License No. 53-16991-01MD

During NRC inspections conducted on February 11, 16-17, March 2 and 7, and April 6-7, 21 and 28, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

A. License Condition 22 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures, including any enclosures, contained in the letter dated April 5, 1989, and letter received October 4, 1991.

Paragraph 1, Item 10-30 of the application included with the letter dated April 5, 1989, requires that only an attache case licensed for use as a Type A shipping container be used to transport radioactive materials.

Contrary to the above, between approximately January 1993 and February 11, 1994, radioactive materials were transported from the parking lots to the nuclear medicine facilities at Honolulu Medical Center and Straub Hospital and Clinic in open cardboard containers, not the Type A attache case.

This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

1. 49 CFR 172.203(d) requires, in part, that the description for a shipment of radioactive material include: (1) the name of each radionuclide, (2) the physical and chemical form of the material, (3) the activity contained in each package of the shipment in terms of curies, millicuries, or microcuries, (4) the category of label applied to each package (e.g., RADIOACTIVE WHITE-I), and (5) the transport index assigned to each package in the shipment bearing RADIOACTIVE YELLOW-II OR -III labels.

a. Contrary to the above, at approximately 8:00 a.m. on February 11, 1994, the licensee transported to Straub Clinic and Hospital a radiopharmaceutical containing 15 mCi of liquid iodine-131 (Lot No. 27496), but the description on the shipping paper that accompanied the shipment did not include the name of the radionuclide, the physical and chemical form of the material, and the activity of the iodine-131 in terms of curies, millicuries, or microcuries.

b. Contrary to the above, on February 11, 1994, the licensee transported to Honolulu Medical Group four radiopharmaceutical vials containing a total activity of 194 mCi of technetium-99m and 1 mCi of iodine-131, but the description on the shipping paper that accompanied the shipment did not include the physical form of the material and the activity contained in each package of the shipment in terms of curies, millicuries, or microcuries.

c Contrary to the above, in two separate shipments at approximately 8:00 a.m. and 10:00 a.m. on February 11, 1994, the licensee transported to Straub Clinic and Hospital a total activity of 507 mCi of technetium-99m, but the description on the shipping paper that accompanied the shipment did not include the name of the radionuclides.

2. 49 CFR 173.475(a) requires that before each shipment of any radioactive materials package, the shipper ensures by examination or appropriate tests that the packaging is proper for the contents to be shipped.

Contrary to the above, on April 19, 1994, the licensee transported outside the confines of its place of use to Kaiser Medical Center, seven cans of radioactive materials, including five cans of technetium-99m (513 mCi) and two cans of thallium-201 (17 mCi), in a Mallinckrodt Diagnostics J716-2 four can box, an improper packaging for the number of containers shipped.

The above items constitute a Severity Level IV violation (Supplement V).

C. License Condition 14 requires, in part, that the licensee shall elute generators in accordance with instructions furnished by the manufacturer in the leaflet or brochure that accompanies the generator.

Contrary to the above, on many occasions between June 1, 1992, and March 2, 1994, the licensee failed to perform an aluminum ion concentration test with a then current test kit each time an elution was made from the licensee's Ultra-Technekow FM technetium-99m generators in accordance with the manufacturer's leaflet (package insert) accompanying each generator.

This is a Severity Level IV violation (Supplement VI).

D. 10 CFR 20.1501(b) requires that the licensee shall ensure that instruments and equipment used for quantitative radiation measurements are calibrated periodically for the radiation measured.

Contrary to the above, as of April 6, 1994, the licensee had not calibrated its wipe test counter which had been used for 2-3 years for making quantitative measurements of removable surface contamination. Specifically, the licensee had not performed the technetium-99m calibration check specified by Section 8 of the manufacturer's

instruction manual.

This is a Severity Level IV violation (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Pacific Radiopharmacy, Ltd., is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region IV, and a copy to the Director, Walnut Creek Field Office, 1450 Maria Lane, Walnut Creek, California, 94596, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Arlington, Texas
this 20th day of May, 1994