



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400  
ARLINGTON, TEXAS 76011-8064

June 10, 1997

Richard H. Naito, R.Ph.  
Pacific Radiopharmacy, Ltd.  
347 North Kuakini Street  
Honolulu, Hawaii 96817

SUBJECT: RESPONSE TO NRC INSPECTION REPORT 030-12031/97-01 AND NOTICE  
OF VIOLATION

Dear Dr. Naito:

Thank you for your letter dated May 19, 1997, in response to our Notice of Violation (Notice) dated April 17, 1997. We have reviewed your reply and find that no further information is needed at this time regarding the violations described in the Notice. We will review the implementation of your corrective actions during a future inspection to determine that full compliance has been achieved and will be maintained.

Should you have any questions concerning this letter please contact Mr. Mark R. Shaffer at (817) 860-8287 or the undersigned at (817) 860-8191.

Sincerely,

A handwritten signature in cursive script, reading "D. Blair Spitzberg".

D. Blair Spitzberg, Ph.D., Chief  
Nuclear Materials Inspection and  
Fuel Cycle/Decommissioning Branch

Docket: 030-12031  
License: 53-16991-01MD

cc: Hawaii Radiation Control Program Director

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PDR ADDCK 03012031  
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Pacific Radiopharmacy, Ltd.

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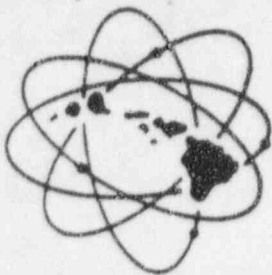
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## PACIFIC RADIOPHARMACY, LTD.

347 NORTH KUAKINI STREET \* HONOLULU, HAWAII 96817  
TELEPHONE (808) 547-9580

May 19, 1997



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

RE: Reply to the Notice of Violation  
Docket : 030-12031  
License: 53-16991-01MD

This letter is in response to a Notice of Violation issued against Pacific Radiopharmacy, Ltd., dated April 17, 1997 and received on April 22, 1997.

A. The violation occurred as stated. Section 9.3, Procedure and Precautions for Radioactive Gases, of the radiopharmacy license states, in part, that the exhaust rate of the exhaust cabinet is at least a continuous 800 cubic feet per minute (cfm). Contrary to the above, on several occasions between January 31, 1996 and February 26, 1997, the exhaust rate was not at a continuous 800 cfm. Specifically, the exhaust fan of the fume hood, which is used to store millicurie quantities of **unopened** xenon-133 and iodine-131, was routinely turned off at the end of each working day, and during times when the radiopharmacy personnel was working in another location of the radiopharmacy (office space located upstairs). The exhaust fan of the downstairs fume hood is now left on at a continuous 800 cfm. This corrective action was in place as of April 1, 1997, right after the final telephonic exit briefing with the inspector Mark R. Shaffer which took place on March 31, 1997.

B. The violation occurred as stated. Section 10.10, Precautionary Measures for Handling Millicurie Quantities of Liquid Radioiodine, of the radiopharmacy license states, in part, that liquid radioiodine solution will be stored and dispensed within a fume hood which has a dedicated ventilation system that vents directly to the exterior. Contrary to the above, on February 26, 1997, approximately 290 millicuries of **unopened** liquid radioiodine solution were stored in the radiopharmacy generator elution room, an area which does not have a fume hood with a dedicated ventilation system. All liquid radioiodine solutions are now stored and dispensed within the downstairs fume hood which has a dedicated ventilation system that vents directly to the exterior. This corrective action was in place as of April 1, 1997, right after the final telephonic exit briefing with the inspector Mark R. Shaffer which took place on March 31, 1997.

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U.S. Nuclear Regulatory Commission

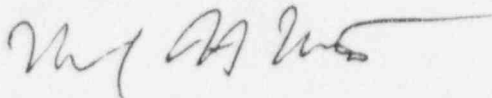
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May 19, 1997

In order to address the violations identified in the Notice of Violation and other aspects related to the radiopharmacy program, it is intended to submit an amendment to the radiopharmacy license.

If there are additional questions regarding this response to the Notice of Violation, please feel free to contact me at (808) 547-9580.

Respectfully,

A handwritten signature in dark ink, appearing to read 'Richard H. Naito', with a long horizontal flourish extending to the right.

Richard H. Naito, RPh, BCNP, RSO  
Radiopharmacist

cc: Regional Administrator, Region IV  
611 Ryan Plaza Drive, Suite 400  
Arlington, Texas 76011