



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

REGION IV

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

MAY 20 1994

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

Licensee: Pacific Radiopharmacy, Ltd.  
347 North Kuakini Street  
Honolulu, Hawaii 96817

Attention: Mr. Calvin Ichinose  
President

SUBJECT: NOTICE OF VIOLATION  
NRC INSPECTION REPORTS 030-12031/94-01 AND 94-02

This refers to the unannounced, special inspections conducted by Mr. David D. Skov and Mr. John Jacobson of this office. The results of Mr. Skov's and Mr. Jacobson's initial inspection were detailed in NRC Inspection Report No. 94-01 which was sent to you previously. The results of Mr. Jacobson's subsequent inspection on April 6-7, 21, and 28, 1994, are detailed in Inspection Report No. 94-02. The inspections included a review of certain activities authorized for your facility in Honolulu, Hawaii. At the conclusion of the inspections, the findings were discussed with those members of your staff identified in the reports. Subsequent discussions relative to the inspections were also held with Dr. Trent T. Phan.

Areas examined during these inspections are described in the reports. Within these areas, the inspections consisted of selective examinations of procedures and representative records, interviews with personnel, and observations of activities in progress. The purpose of the inspections was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements.

Based on the results of these inspections, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation (Notice). The violations are of concern because they demonstrate a lack of attention to detail by the radiopharmacy staff. The failure to properly identify the radioactive materials being shipped is of concern because of the confusion that may occur following receipt at a client's facility or if a package were lost or involved in an accident. The violations for failure to limit the number of containers in each shipping package, and failure to ensure the use of only those shipping packages that comply with DOT and NRC license requirements are also of concern because of the potential consequence to the safe transportation of radioactive materials. The violations involving failure to perform the aluminum ion concentration test for generator eluates and to properly calibrate a contamination measurement instrument indicate weakness in your quality control program.

A violation of License Condition 22.A for failure to wipe the exterior of a package of radiopharmaceuticals is not being cited because of your Radiation

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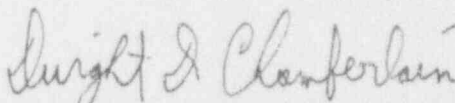
Protection Officer's prompt commitment to wipe the package exterior, in addition to wiping individual containers, and because the enforcement discretion criteria in Section VII.B.1 of the Enforcement Policy were satisfied.

Although you described your actions taken in response to Inspection Report No. 94-01 in a letter dated April 15, 1994, you are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. Your response should document the specific actions taken and any additional actions you plan to prevent recurrence of these violations. Also, in your reply you should describe those actions taken or planned to improve the effectiveness of your overall management control system. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,



*fr* Samuel J. Collins, Director  
Division of Radiation Safety  
and Safeguards

Enclosures:

1. Notice of Violation
2. NRC Inspection Report  
030-12031/94-02

bcc w/Enclosure and IFS Form:  
Docket File  
Inspection File  
Y. Elko, RIV Arlington (original IFS)

bcc w/Enclosure:  
J. Callan, RIV Arlington  
S. Collins, RIV Arlington  
G. Sanborn, RIV Arlington  
K. Perkins, WCFO  
R. Huey, WCFO  
G. Cook, WCFO  
State of Hawaii

bcc w/o Enclosure:  
M. Smith, WCFO

<i>Jmf</i> J. Jacobson 5/12/94	<i>DSkov</i> D. Skov 5/12/94	<i>GPY</i> G. Yuhas 5/12/94	<i>JCW</i> J. Wenslawski 5/13/94	<i>SCollins</i> S. Collins 5/18/94
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YES / NO ]	YES / NO ]	YES / NO ]	YES / NO ]	YES / NO ]

SEND TO DCS ]	SEND TO PDR ]
YES / NO ]	YES / NO ]