

DMB

JUN 28 1994

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

Pacific Radiopharmacy, Ltd.
ATTN: Calvin Ichinose
President
347 North Kuakini Street
Honolulu, Hawaii 96817

SUBJECT: NRC INSPECTION REPORTS 030-12031/94-01 and 94-02

Thank you for your letter of June 17, 1994, in response to our letter and Notice of Violation dated May 20, 1994. We have reviewed your reply and find it responsive to the concerns raised in our Notice of Violation. 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.

Sincerely,

Original signed by
F. A. Wenslawski, Chief
Materials Branch
Division of Radiation Safety
and Safeguards

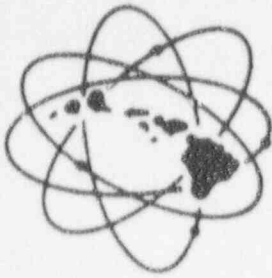
cc:
State of Hawaii

bcc:
DMB - Original (IE-07)
LJCallan
SJCcollins
RAScarano
DWeiss, OC/LFDCB (T-9E10)
WLFisher
CLCain
FAWenslawski
Inspector
NMIB
MIS System
WCFO Files (2)

WCFO	C:MLB <i>gaw</i>	DCS
GYuhas <i>GRX</i>	FAWenslawski	Yes/No
6/15/94	6/28/94	

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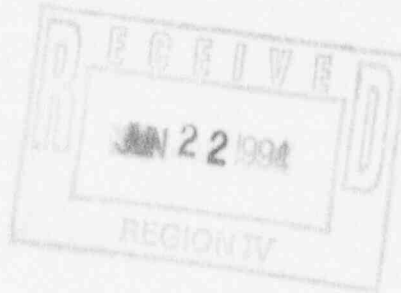
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PACIFIC RADIOPHARMACY, LTD.

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.

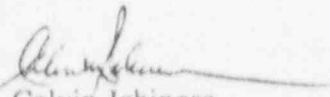
A program was started for RPO review of shipping papers in conjunction with another member of the staff prior to package shipment. As previously mentioned, a new member of the staff was hired to answer the telephone and assist with some of the paper work in order to provide more time in the mornings 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.

Letter to U.S. Nuclear Regulatory Commission
June 17, 1994
Page 4

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



UNITED STATES
NUCLEAR REGULATORY COMMISSION

Socket File

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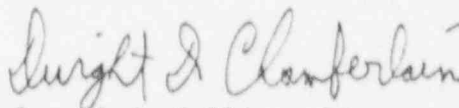
Protection Officer's prompt commitment to wipe the package exterior, in addition to wiping individual containers, and because the enforcement discretion criteria in Section VII.B.1 of the Enforcement Policy were satisfied.

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 2.797 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>gmj</i> J. Jacobson 5/12/94	<i>g</i> D. Skov 5/12/94	<i>GPV</i> G. Yuhas 5/12/94	<i>JCW</i> F. Wenslawski 5/13/94	<i>JP</i> S. Collins 5/18/94
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REQUEST COPY] YES / NO]	REQUEST COPY] YES / NO]	REQUEST COPY] YES / NO]	REQUEST COPY] YES / NO]	REQUEST COPY] YES / NO]
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SEND TO DCS] YES / NO]	SEND TO PDR] YES / NO]
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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.

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- 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