APPENDIX B

U. S. NUCLEAR REGULATORY COMMISSION
REGION IV

Report No.: 30-12031/94-02

License No.: 53-16991-01MD

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

Facility Name: Pacific Radiopharmacy

Inspection at: Pacific Radiopharmacy
Address Above

Inspection Conducted: April 6-7, 21 and 28, 1994

Inspector: John M. Jacobson, Radiation Specialist, Materials Branch
Walnut Creek Field Office

Approved by: Frank A. Wenslawski 5/13/94
Frank A. Wenslawski, Chief Date Signed
Materials Branch

Inspection Summary

Areas Inspected: This was an unannounced, special inspection of Pacific Radiopharmacy (PRP). Areas covered during the inspection included surveys, receipt records, and transportation of radioactive materials.

Results:

* The licensee's surveys, records of receipt, and shipment of radioactive materials met NRC requirements with three exceptions. The exceptions involved the following:

  * failure to survey the exterior of shipping packages for removable contamination;

  * failure to properly calibrate a contamination measuring instrument; and,

  * placement of more radiopharmaceutical containers in shipping boxes than they have been certified to accommodate.

Summary of Inspection Findings:

* (Closed) Non-Cited Violation: Failure to survey (wipe test) the external

surface of a package of radiopharmaceuticals on April 6, 1994, as required by License Condition 22.A (Section 1).

* (Open) Violation 94-02-01: Failure to perform the Tc-99m calibration check for the licensee's Nuclear Associates Deluxe Wipe Test Counter, Model No. 05-578, as of April 6, 1994, as required by 10 CFR 20.1501(b) (Section 1).

* (Open) Violation 94-01-02: Failure to ensure that the packaging is proper for the contents to be shipped on April 19, 1994, as required by 10 CFR 71.5 and 49 CFR 173.475(a). This is an addition to the open DOT violation identified in NRC Inspection Report No. 94-01. (Section 3.)

Attachment:

* Attachment 1 - Persons Contacted and Exit Meeting

DETAILS

1 SURVEYS

The inspector reviewed selected shipment, receipt, and weekly contamination survey records for 1993 and 1994, and observed licensee surveys for compliance with requirements in 10 CFR Part 20 and applicable license conditions. Based on the review of survey records, the licensee appears to be performing wipe tests for materials leaving the facility and upon receipt, and performing weekly removable contamination surveys. The inspector observed the Radiation Protection Officer (RPO) taking wipes of the outer surfaces of all the radiopharmaceutical containers placed into a package for transport for the second delivery run on April 6, 1994, instead of the exterior surface of the package. The RPO stated that he always wiped the containers and sometimes the exterior of the package. Other individuals interviewed stated they wiped both the containers and the exterior of packages leaving the radiopharmacy. The inspector pointed out that paragraph 5 of Item 10-28 of the license application dated April 5, 1989, states that the exterior of the package will be checked for loose surface contamination. Although the RPO's procedure is more conservative than the license condition, he is nevertheless required to smear the exterior of the package or submit an amendment request for deletion of this requirement. The RPO stated that the exterior of the packages are wiped for the first delivery each morning, but that he would do it for all deliveries in the future.

Paragraph 5 of Item 10-28 of the application dated April 5, 1989, incorporated into the license as License Condition 22.A requires, in part, that the licensee check the exterior of the package for loose surface contamination. Contrary to the above, the licensee's RPO failed to wipe the exterior of the package of radiopharmaceuticals for the second delivery run on April 6, 1993. This violation is not being cited because of the licensee's prompt commitment to wipe the exterior of the package in addition to the individual radiopharmaceutical containers, and because the criteria in Section VII.B.1 of the Enforcement Policy were met.

The inspector observed the RPO counting a number of wipes using the licensee's Nuclear Associates Deluxe Wipe Test Counter, Model 05-578. The counter is a thin-window Geiger-Mueler (GM) tube for detecting beta and gamma contamination. The counter contains preprogrammed efficiencies for a number of common isotopes. When operated in the "KDPM" mode, the counter will respond with either a pass or fail condition for a threshold value set by the user for the isotope(s) of interest. The RPO has set the counter for a threshold corresponding to 200 dpm for iodine-131 (I-131) which corresponds to 10^{-6} uCi/cm^2 for a 100 cm^2 wipe. This puts the licensee below the surface contamination limits for packages in 49 CFR 173.443 and at the recommended level for unrestricted areas in medical institutions in accordance with Table 2 of Regulatory Guide 8.23. To assure proper operation of the counter, the manufacturer provides a 1-uCi cesium-137 check source which the licensee counts daily.

The manufacturer's instruction manual also specifies that the owner perform a

technetium-99m (Tc-99m) calibration check upon receipt of the device to ensure that the counter's efficiency is in fact that which the manufacturer has preprogrammed into it. This is an important test since all the thresholds for other isotopes are determined using conversion factors relative to Tc-99m. In response to NRC Information Notice 93-30, "NRC REQUIREMENTS FOR EVALUATION OF WIPE TEST RESULTS; CALIBRATION OF COUNT RATE SURVEY INSTRUMENTS," the manufacturer mailed a service memo dated November 5, 1993, to users of the wipe test counter emphasizing the need to perform the Tc-99m calibration check. A copy of the memo, received by the RPO, states: "If the isotope you are surveying for is included in the following table [which includes the I-131 efficiency, conversion factor, and LLD (lower limit of detection)] and you have performed the Tc-99m Calibration Check, then the NRC requirement for efficiency determination has been satisfied." The RPO stated that the radiopharmacy had been using the wipe test counter for 2-3 years, but had not performed the Tc-99m calibration check in Section 8 of the instruction manual due to an oversight.

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. The licensee's failure to calibrate its wipe test counter used for making quantitative measurements of removable surface contamination is a violation of this requirement. Specifically, the licensee had not performed the Tc-99m calibration check specified in Section 8 of the manufacturer's instruction manual, although the instrument had been in use for 2-3 years. (94-02-01)

The inspector also reviewed the licensee's daily dose rate survey records and noted that the values changed over time, but none exceeded about 0.05 mr/hr. The licensee had a calibrated and operational instrument available for these surveys. The inspector used the licensee's most recent survey record and performed his own surveys of the facility using a Ludlum Model 3 (NRC Serial No. 022879, calibrated on 3/7/94) with a GM tube and pancake probe. The inspector obtained dose rates comparable to those documented by the licensee and did not detect any significant contamination.

One violation and one non-cited violation were identified during the review of this program area.

2 RECEIPT RECORDS

While performing independent surveys, the inspector noted that a large number of old radiopharmaceutical containers and vials were stored at the licensee's facility. The inspector questioned the RPO about them and he stated that Pacific Radiopharmacy often takes back radiopharmaceuticals that its clients do not use. The inspector reviewed selected records from the licensee's file of doses returned from clients for the period from August 1992, to April 1994. Based on this review, the licensee appears to have receipt records for returns. However, the inspector noted that many of the radiopharmaceuticals returned had gone through at least ten half-lives. The inspector questioned the RPO as to why the licensee had not disposed of these old vials and syringes. The RPO stated that he intended to do so, but had not had enough time and was concerned about making a mistake after an incident in November

1992, in which licensed materials had been thrown in the non-radioactive trash and set off an alarm at the H-Power transfer station. The number of radiopharmaceutical containers, vials, and syringes which the licensee is currently storing on its premises, and which have little or no residual activity, is of concern because of the potential that a container with radioactive material could be inadvertently placed among the containers with none. This concern was expressed to the licensee at the exit meeting.

No violations or deviations were identified during the review of this program area.

3 TRANSPORTATION OF RADIOACTIVE MATERIALS

On April 19, 1994, the licensee delivered a package of radiopharmaceuticals to Kaiser Medical Center in a labeled DOT 7A cardboard box. The technologist at Kaiser noticed the presence of seven containers of radioactive materials, including 5 containers of Tc-99m (totaling 513 mCi) and 2 containers of Tl-201 (totaling 17 mCi), in a four can box. In a telephone conversation with the inspector on April 21, 1994, the RPO stated that the licensee has been shipping radiopharmaceuticals in cardboard boxes approved as DOT 7A Type A packages for 2-can and 4-can configurations. The boxes are designed by Mallinckrodt Diagnostics of Mallinckrodt, Inc. to enclose 1 or 2 containers or 4 containers packed in top and bottom absorbent foam inserts. Mallinckrodt has performed the tests pursuant to 49 CFR 173 for the one or two can box (J718-1) and the four can box (J716-2), and documented the results to certify that the boxes are DOT 7A packages when loaded with the proper number and configuration of containers and the proper foam inserts. The RPO stated that the licensee has been removing the top foam insert, placing more than the 2 or 4 containers in the package, and filling in the top of the package with styrofoam beads or paper towels for absorbent material. The RPO stated that this was done because the licensee needed to ship varying numbers of vials to its customers each day and was not aware that the contents of the Type A boxes could not be changed without performing the required tests for Specification 7A packagings. The RPO also stated that many of the licensee's lead pigs were 1.5 inches in diameter as opposed to Mallinckrodt's 2.75-inch-diameter containers, and thus do not fit snugly into the cut-outs in the foam inserts accompanying the boxes. In a subsequent telephone conversation on April 28, 1994, the RPO stated that he was performing the tests required to certify that the configuration of the two can and four can boxes and containers he is using meet the requirements for a Specification 7A Type A package and would retain the results of the certification on file.

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. 49 CFR 173.475(a) requires that before each shipment of any radioactive materials package, the shipper shall ensure by examination or appropriate tests, that the packaging is proper for the contents to be shipped. The licensee's transportion of 7 cans of radioactive materials in a Mallinckrodt Diagnostics J716-2 four can box is an improper packaging for the number of cans being

shipped, and is a violation of the requirements stated above. This finding is in addition to the open violation (94-01-02) identified in NRC Inspection Report No. 94-01.

ATTACHMENT 1

1 PERSONS CONTACTED

1.1 Licensee Personnel

*Trent T. Phan, Ph.D., Radiopharmacist and Radiation Protection Officer (RPO)
John Tani, Driver
Erik Laride, Technician and Driver

1.2 NRC Personnel

*Eugene J. Power, Office of Investigations, Walnut Creek Field Office
*John Jacobson, Radiation Specialist, Walnut Creek Field Office

* Denotes personnel that attended the exit meeting.

2 EXIT MEETING

An exit meeting was held with the RPO on April 7, 1994. The inspector discussed the failure of the licensee to perform a Tc-99m calibration check for the wipe test counter. The RPO stated that he now realized the check had to be done and that the licensee would perform the check. The inspector also reminded the RPO of the requirement to wipe the external surface of packages containing radioactive materials.

In a telephone conversation with the RPO on April 21, 1994, the inspector discussed the requirment that the licensee ensure that the packaging used to transport radioactive materials is appropriate for the contents shipped. In a subsequent telephone conversation on April 28, 1994, the RPO stated that he was performing the Specification 7A tests to certify that the boxes he is using are DOT 7A, Type A packagings for the types and number of radiopharmaceutical containers he transports in them. He also stated that he would retain this certification on file.

No proprietary information was provided by the licensee during this inspection.