



July 24, 2001

Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, DC 20555

Subject: Reply to a Notice of Violation

To: U.S. Nuclear Regulatory Commission:

Three violations of NRC requirements were identified in our facility during an NRC inspection conducted on May 8 and 10, 2001. The violations and corrective actions are listed below:

1. Section 3 of appendix H states that the licensee staff shall monitor hands and clothing for contamination before leaving a restricted area. Several licensee staff were not monitoring hands or clothing (shoes) prior to leaving a restricted area.
 - a. All restricted entrances and exits have been posted with signs reading "door must remain closed at all times" and "monitor hands and feet before leaving." In addition, at all staff meetings a reminder is given to all staff members that they must continue to monitor hands and feet every time they leave the restricted area, and keep the door closed.
 - b. A spring-loaded hinge has replaced the original hinge at the main restricted exit. This will help the staff members to close the door.
2. The licensee failed to replace disposable charcoal filter traps and the disposable charcoal air filters used for the restricted and unrestricted effluent monitoring system for an extended period of time. In addition, the licensee did not appropriately analyze the quantity of iodine-131 on these filters.
 - a. The manager and staff pharmacist are changing the filters for both the restricted and unrestricted effluent systems on a weekly basis. We will keep a sufficient supply of these filters in order to replace them weekly.

- b. We changed the method of analyzing these filters by increasing the effective counting area of the detector used to measure the iodine-131. We stopped using the well counter, which had an effective counting area of approximately 0.8 cm and are now using the thyroid probe detector without the collimator, which increased the effective counting area to 25.7 cm. The probe is placed directly on the charcoal filters and source.
 - c. The licensee failed to evaluate appropriate monitoring and controls when members of the general public occupied offices in the same building occupied by the licensee. Monitoring of direct radiation exposure is done daily by using the survey meters. The survey meter readings have all been background. The radioactive material is stored on the opposite side of the building giving the neighbors no exposure. We documented the indirect radiation exposure using the EPA Comply program. We used the past six months of data starting in December 2000 from the restricted and unrestricted charcoal filters. The results were attached to the letter received by the Region III office on May 29th. We passed the Comply program. Because the data was from charcoal filters that were not changed weekly, we will rerun the Comply program at the end of August 2001. This will give us three months of data.
3. The licensee was not placing the detector against the front of the neck when performing thyroid counting. Specifically, the licensee used a detector equipped with a collimator, which held the detector approximately 9 inches from the neck when performing thyroid bioassay. All of the staff have been trained on the proper technique for bioassay. The thyroid probe is placed directly against the front of the neck.

All of the above corrective actions were completed the week of May 14th, 2001.

Sincerely,



Christopher Leon
Pharmacy Manager
Pharmalogic MI

cc: Regional Administrator Region III
Bill Chatoff, President



PharmaLogic MI, L.L.C.
1144 Boon Street
Traverse City, MI 49686

CERTIFIED MAIL



7000 0520 0021 6924 5085



9264



20555

U.S. POSTAGE
PAID
TRAVERSE CITY, MI
49686
JUL 25 '01
AMOUNT

\$3.94
00011224-92

Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, DC 20555

**RETURN RECEIPT
REQUESTED**