

Reply to a Notice of Violation

November 3rd, 2006

U.S. Nuclear Regulatory Commission Materials License No. 44-30124-01MD

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

Subject: Response to Docket No. 03033449

To Whom It May Concern:

Stephen Hammann, of the U.S. Nuclear Regulatory Commission, conducted a safety inspection of our Pharmalogic, Ltd. facility in Williston, Vermont (hereafter referred to as Pharmalogic) on September 17, 2006.

We received a Notice of Violation(s) on October 12th, 2006 from James P. Dwyer, Chief of the Commercial and R&D Branch, Division of Nuclear Materials Safety of Region I of the U.S. Nuclear Regulatory Commission, which was dated October 5th, 2006. In the Notice of Violation, there was one violation listed specifically for Pharmalogic, Ltd.

The violation will be addressed, with (1) the reason for the violation presented (copied directly from the Notice of Violation), (2) the corrective steps that have been taken and any results achieved noted, (3) the corrective steps that will be taken to avoid future violations, and (4) the date when full compliance will be achieved.

Violation:

(1):

During an NRC inspection conducted on September 17, 2006, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR Part 20.1101(c) requires that the licensee shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, no annual program review was performed since prior to the inspection conducted in July 2003.

This is a Severity Level IV violation (Supplement IV).

LE07

(2):

In an effort to correct the above violation, Pharmalogic has started an in-house review of its radiation protection program content and implementation (i.e., an employee(s) of the Pharmalogic, Ltd. Vermont facility is performing the review).

(3):

The following corrective steps will be taken to avoid this violation in the future:

- a) A review of Pharmalogic's radiation protection program content and implementation will be completed by December 31st each year.
- b) This review will be performed (if possible) by a professional who is not a full-time employee of Pharmalogic, Ltd. (Vermont facility). If it is not possible for this to occur by October 31st of each year, a suitable employee of Pharmalogic, Ltd. (Vermont facility) will perform the review by December 31st of that year.

(4):

Full compliance as described in part (2) will be achieved by December 31st, 2006. The corrective steps put forward in part (3) will be put into effect on January 1, 2007.

If my manager, Tom DeFranco, or I can be of more assistance to the NRC, please don't hesitate to contact us at Pharmalogic, Ltd. We can be reached by phone at 802-862-9944, or by e-mail at pharmalogicltd@yahoo.com.

Sincerely,



Stephen Sopchak, R.Ph., RSO
Pharmalogic, Ltd.
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