UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

October 8, 2005

Docket No. 03033449 License No. 44-30124-01MD

Thomas Defranco, R.Ph.
Manager
Pharmalogic LTD
9 Krupp Drive
Williston, VT 05495

SUBJECT: INSPECTION 03033449/2005001, PHARMALOGIC LTD, WILLISTON, VERMONT SITE AND NOTICE OF VIOLATION

Dear Mr. Defranco:

On August 23, 2005, Todd Jackson of this office conducted a safety inspection at the Williston, Vermont address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selected examination of representative records. Additional information relevant to the inspection findings was provided to Mr. Jackson during a telephone conversation on October 5, 2005. The findings of the inspection were discussed with you and your Radiation Safety Officer, Mr. Stephen Sopchak, at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed that categorizes each violation by severity level. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. 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.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, industrial, and academic uses of nuclear material;** then **toolkit index page.** The Current General Policy and Procedure for NRC Enforcement Actions are included on the NRC's website at www.nrc.gov; select **What We Do, Enforcement,** then **Enforcement Policy.** Or you may obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-888-293-6498. The GPO is open from 7:00 a.m. to 9:00 p.m. EST, Monday through Friday (except Federal holidays).

Your cooperation with us is appreciated.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
Stephen Sopchak, Radiation Safety Officer
State of Vermont

Distribution:
D. J. Holody, RI

DOCUMENT NAME: E:\Filenet\ML052850203.wpd

SISP Review Complete: TJJ
After declaring this document "An Official Agency Record" it **will** be released to the Public.

To receive a copy of this document, indicate in the box: "**C**" = Copy w/o attach/encl "**E**" = Copy w/ attach/encl "**N**" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	Tjackson/TJJ		JDwyer.JPD					
DATE	signed on 10/5/2005		10/8/2005					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Pharmalogic LTD
Williston, VT

Docket No. 03033449
License No. 44-30124-01MD

During an NRC inspection conducted on August 23, 2005, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 20.1502(b)(1) requires that each licensee monitor the occupational intake of radioactive material by and assess the committed effective dose equivalent to adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable annual limit of intake (ALI) in Table 1, Columns 1 and 2, of Appendix B to §§ 20.1001-20.2402.

10 CFR 20.1204(a) requires, for purposes of assessing dose used to determine compliance with occupational dose equivalent limits, that the licensee shall, when required under § 20.1502, take suitable and timely measurements of --

(1) Concentrations of radioactive materials in air in work areas;
(2) Quantities of radionuclides in the body;
(3) Quantities of radionuclides excreted from the body; or
(4) Combinations of these measurements.

Contrary to the above, as of August 23, 2005, the licensee did not monitor the occupational intake of radioactive material by and assess the committed effective dose equivalent to adults likely to receive, in 1 year, an intake in excess of 10 percent of the applicable ALI by making suitable and timely measurements of (1) concentrations of radioactive materials in air in work areas; (2) quantities of radionuclides in the body; (3) quantity between 3.2 and 4 curies of iodine-131 sodium iodide each month, and who therefore were likely to receive, in 1 year, an intake in excess of 10 percent of the inhalation ALI of 50 microcuries, by making measurements of the quantity of iodine-131 in the body in an inaccurate and irreproducible manner. For example:

(1) Calibration of the system used to monitor the thyroid is inadequate. Calibration utilized a small iodine-131 capsule that could be placed in a variable position relative to the detector resulting in calibration factors ranging from 2419 up to 13,123 cpm/microcurie. Additionally, high voltage settings were not controlled by procedure, which could cause the calibration factor to change in an uncontrolled manner;

(2) Detector background count rate varied significantly and in an uncontrolled manner, based on the background count rates recorded. Background could vary between the time background was measured and the time the thyroid measurements were made. The detector, while collimated to focus on the thyroid and minimize background influences from elsewhere in the controlled area, was pointed at the table upon which receipt surveys for incoming packages containing radioactive material were performed. If packages are being surveyed or opened during some portion of the bioassay procedure, a short-term

fluctuation in background could affect measurements in an undetermined amount.

(3) Background measurements were made with the detector placed on the chest. This practice may contribute to background variability because placement on the chest may be over muscle or lung tissue, each of which will likely produce different background count rates. An alternative practice widely used is to measure background with the detector placed against the large muscle of the thigh. This also reduces the influence on background from any radioactive iodine in the thyroid since the thigh is farther away from the thyroid.

(4) Recorded measurement data was incomplete. Two different scalars were used with the bioassay detector since July 2003 to make bioassay measurements, although records only indicate one serial number for all measurements. The date when the scalars were exchanged is not recorded. Additionally, only average background and net thyroid counts were recorded, making it impossible to verify manual calculations.

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

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

Contrary to the above, as of August 23, 2005, no periodic audits of the radiation safety program had been performed since the last NRC inspection on July 2, 2003

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

C. 10 CFR 32.72©) requires that a licensee that manufactures, prepares, or transfers for commercial distribution radioactive drugs containing byproduct material for use by persons authorized pursuant to 10 CFR Part 35: (1) possess and use instrumentation to measure the radioactivity of radioactive drugs; (2) have procedures for use of the instrumentation; and (3) measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall:

(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and

(2) Check each instrument for constancy and proper operation at the beginning of each day of use.

Contrary to the above, as of August 23, 2005, the licensee did not have procedures for use of the instrumentation to measure the radioactivity of radioactive drugs. Specifically, on two occasions the results of dose calibrator accuracy testing were greater than the indicated acceptance criteria of ±5% and no corrective action was taken. The licensee was not able to provide a procedure defining corrective actions to be taken in response to measurements outside the acceptance criteria.

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

Pursuant to the provisions of 10 CFR 2.201, Pharmalogic 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 I, 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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to 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.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days.

Dated This _8th_ day of _October_ 2005