REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

March 25, 2009

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

Thomas DeFranco, R.Ph.
Manager/Radiation Safety Officer
PharmaLogic Ltd.
9 Krupp Drive
Williston, VT 05495

SUBJECT: NRC INSPECTION REPORT NO. 03033449/2009001, PHARMALOGIC LTD., WILLISTON, VERMONT SITE AND NOTICE OF VIOLATION

Dear Mr. DeFranco:

On March 4, 2009, Thomas Thompson of this office conducted a safety inspection at the above address of activities authorized by your 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 selective examination of representative records. Additional information provided in your correspondence dated March 5, 2009, was also examined as part of the inspection. The findings of the inspection were discussed with you 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 the violations 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.

Item A in the Notice of Violation enclosed with this letter was identified during a previous inspection of your licensed activities and documented in a Notice of Violation enclosed with our letter dated October 24, 2007. From this inspection, it appears that your corrective actions were not effective since this item has recurred. Therefore, in your response to this letter, you should give particular attention to those actions taken or planned to ensure that identified items of noncompliance will be completely corrected and will not recur.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications Page.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC; How We Regulate; Enforcement;** then **Enforcement Policy.** You may also obtain these documents by contacting the Government

Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Thomas K. Thompson at 610 337-5303 if you have any questions regarding this matter.

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:
State of Vermont

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Enclosure:
Notice of Violation

cc:
State of Vermont

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NAME	TThompson/JDP f/		JDwyer/JDP					
DATE	3/25/2009		3/25/2009					

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

PharmaLogic Ltd.
Williston, VT

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

During an NRC inspection conducted on March 4, 2009, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Contrary to the above, on March 4, 2009, the licensee did not make surveys to assure compliance with 10 CFR 20.1201(a)(2)(ii), which limits shallow-dose to the skin of the whole body or to the skin of the extremities to 50 rems. Specifically, a licensee pharmacist failed to monitor his hands before exiting the area controlled for contamination where multiple curies of technetium-99m and multiple millicuries of iodine-131 are regularly handled. When the pharmacists hands were surveyed by the inspector in the unrestricted area, an area of radioactive material contamination was identified.

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

B. 10 CFR 20.2104(a)(1) and 20.2104(a)(2) require, in part, that for each individual who is likely to receive in a year an occupational dose requiring monitoring pursuant to 10 CFR 20.1502, the licensee shall determine the occupational radiation dose received during the current year and attempt to obtain the records of cumulative occupational radiation dose.

Contrary to the above, as of March 4, 2009, for each individual who was likely to receive in a year an occupational dose requiring monitoring pursuant to 10 CFR 20.1502, the licensee did not determine the occupational radiation dose received by the individual during the current year. Specifically, one radiopharmacist worked and received occupational exposure at the licensee's Williston facility and at another licensed facility yet the licensee did not know the total exposure received by the radiopharmacist during the period of January 1, 2009 through March 4, 2009.

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 25 day of March 2009