



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

May 5, 2008

Docket No. 03034418

License No. 29-30383-01

Stephen T. Wills
Chief Financial Officer
Palatin Technologies, Inc.
4-C Cedar Brook Drive
Cedar Brook Corporate Center
Cranbury, NJ 08512

**SUBJECT: INSPECTION 03034418/2008001, PALATIN TECHNOLOGIES, INC.,
CRANBURY, NEW JERSEY SITE AND NOTICE OF VIOLATION**

Dear Mr. Wills:

On March 5, 2008, Dennis Lawyer of this office conducted a safety inspection at the above 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 provided in your correspondence dated March 11, 13, 17, and 25, 2008, and the telephone conversation on May 2, 2008 between Maria Schiltz, Ph.D. of your organization and this office, were also examined as part of the inspection. The findings of the inspection were discussed with Dr. Schiltz 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. In addition to the violation cited in the enclosed Notice, one non-repetitive, licensee identified and corrected violation, related to exceeding the license possession limit for carbon-14, is being treated as a Non-Cited Violation (NCV) consistent with Section VI.A.8 of the Enforcement Policy.

If you contest the violation cited in the enclosed Notice or the significance of the NCV, you should provide a response within 30 days of the date of this inspection report, with the basis for your denial, to the Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington DC 20555-0001, with copies to: (1) the Regional Administrator, Region 1; and (2) the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Another area of concern identified by the inspector had to do with the receipt of labeled packages. The inspector observed an individual employee survey a Radioactive White-I labeled package using a survey meter equipped with a sodium iodide probe. Because of the over response to radiation caused by the sodium iodide probe, the individual noted a survey result that was far greater than the 0.5 millirem per hour maximum on contact radiation level that is allowed by the Department of Transportation for a Radioactive White-I package. When questioned by the inspector, the individual was aware of the 200 millirem per hour maximum contact radiation level that was permitted on a Radioactive Yellow-III package but was apparently unaware that Radioactive White-I and Radioactive Yellow-II packages had lower contact radiation level limits. This concern was not identified as a violation because the survey the individual performed was not required by the regulations or the conditions of your license.

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; Organization and Functions; Office of Enforcement; About 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 8:00 p.m. EST, Monday through Friday (except Federal holidays).

Please contact Dennis Lawyer at 610-337-5366 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:
Maria Schiltz, Ph.D., Radiation Safety Officer
State of New Jersey

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

Enclosure:
Notice of Violation

cc:
Maria Schiltz, Ph.D., Radiation Safety Officer
State of New Jersey

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OFFICE	DNMS/RI	N	DNMS/RI				
NAME	DLawyer/drl		JDwyer/jpd				
DATE	05/05/2008		05/05/08				

NOTICE OF VIOLATION

Palatin Technologies, Inc.
Cranbury, NJ

Docket No. 03034418
License No. 29-30383-01

During an NRC inspection conducted on March 5, 2008, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 20.1101(c) requires the licensee to periodically (at least annually) review the radiation protection program content and implementations.

Contrary to the above, as of March 5, 2008, the licensee did not perform a review of the radiation protection program content and implementations at least annually. Specifically no program review had been performed since December 13, 2006 and there was no program and implementation review performed in 2007.

Severity Level IV violation (Supplement IV)

Pursuant to the provisions of 10 CFR 2.201, Palatin Technologies, Inc. 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 5 day of May 2008