



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

February 9, 2005

Docket No. 03035323

License No. 41-30557-01

Ashok Dhar  
Head, Regulatory Compliance  
P.E.T. Net Pharmaceuticals, Inc.  
810 Innovation Drive  
Knoxville, TN 37932-2571

**SUBJECT: INSPECTION 03035323/2005001, P.E.T. NET PHARMACEUTICALS, INC.,  
NORTH WALES, PENNSYLVANIA SITE AND NOTICE OF VIOLATION**

Dear Mr. Dhar:

On February 3 and 4, 2005, Steven Courtemanche of this office conducted a telephone interview with staff who work in your facility located at 398-402 Industrial Drive, Upper Gwynedd Industrial Park, North Wales, Pennsylvania. Activities at this facility are conducted under the NRC license listed above. The interview 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. Additional information provided in your correspondence dated February 3, 2005, 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 in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600. 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 and preventive 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.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the NRC Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or [pdr@nrc.gov](mailto:pdr@nrc.gov).

A. Dhar  
P.E.T. Net Pharmaceuticals, Inc.

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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:  
Robert Durkin, Acting Radiation Safety Officer  
State of Tennessee  
Commonwealth of Pennsylvania

A. Dhar  
P.E.T. Net Pharmaceuticals, Inc.

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D. J. Holody, RI

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OFFICE	DNMS/RI	N	DNMS/RI				
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DATE	02/04/2005		2/9/05				

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## NOTICE OF VIOLATION

P.E.T. Net Pharmaceuticals, Inc.  
Knoxville, TN

Docket No. 03035323  
License No. 41-30557-01

During a telephone inspection conducted on February 3 and 4, 2005, two violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violations are listed below:

- A. Condition 11 of License No. 41-30557-01 requires that the Radiation Safety Officer for this license is Lory Hansen, R.Ph., Ph.D.

Contrary to the above, between May 2004 and February 3, 2005, the Radiation Safety Officer for this license was not Lory Hansen, R.Ph., Ph.D. Specifically, Dr. Hansen left the employ of the licensee in May 2004 and the licensee did not request amendment of the license to name a new Radiation Safety Officer until February 3, 2005.

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

- B. Condition 12 of License No. 41-30557-01 requires that licensed material be used by, or under the supervision of, Lory Hansen, R.Ph., Ph.D.

Contrary to the above, between May 2004 and February 3, 2005, licensed material was not used by, or under the supervision of Lory Hansen, R.Ph., Ph.D. Specifically, Dr. Hansen left the employ of the licensee in May 2004 and the licensee did not request amendment of the license to name a new authorized user until February 3, 2005.

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

Pursuant to the provisions of 10 CFR 2.201, P.E.T. Net Pharmaceuticals, 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.

Notice of Violation  
P.E.T. Net Pharmaceuticals, Inc.

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Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site at <http://www.nrc.gov/reading-rm.html>. 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 9 day of February 2005