



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

December 3, 2004

Docket No. 03034650

License No. 45-25425-01

Frank P. Simione, Vice President
Management and Compliance Services
American Type Culture Collection
10801 University Blvd.
Manassas, VA 20110-2209

**SUBJECT: INSPECTION 03034650/2004001, AMERICAN TYPE CULTURE COLLECTION,
MANASSAS, VIRGINIA SITE AND NOTICE OF VIOLATION**

Dear Mr. Simione:

On November 18, 2004, Thomas Thompson and Steve Hammann 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 selected examination of representative records. The findings of the inspection were discussed with you and Dr. Judith A. Kantor 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 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 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.

F. Simone
American Type Culture Collection

2

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:
Judith A. Kantor, Radiation Safety Officer
Commonwealth of Virginia

F. Simone
American Type Culture Collection

3

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OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	Tthompson/jpd for:		JDwyer/jpd					
DATE	12/03/04		12/03/04					

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NOTICE OF VIOLATION

American Type Culture Collection
Manassas, VA

Docket No. 03034650
License No. 45-25425-01

During an NRC inspection conducted on November 18, 2004, one violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violation is listed below:

Condition 12 of License No. 45-25425-01 requires that the Radiation Safety Officer for this license is Robert J. Hay, Ph.D.

Contrary to the above, on November 18, 2004, the Radiation Safety Officer for License No. 45-25425-01 was not Robert J. Hay, Ph.D.. Specifically, or about April 2004, Robert J. Hay, Ph.D. left the employment of American Type Culture Collection and, prior to receiving NRC approval, the licensee appointed another individual to serve as the Radiation Safety Officer.

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

Pursuant to the provisions of 10 CFR 2.201, American Type Culture Collection 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 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 3rd day of December 2004