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December 22, 2004

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington, DC 20555-0001

Re: Reply to Notice of Violation
Notice of Violation Docket No. 03034650
ATCC License No. 45-25425-01

Attn: Document Control Desk

The above notice of violation was received after an inspection of ATCC facilities on November 18, 2004, and this response is in compliance with 10 CFR 2.201.

- 1) ATCC was cited for violation of condition 12 of license No. 45-25425-01 that required that the Radiation Safety Officer for the license be Dr. Robert J. Hay. Dr. Hay was the Radiation Safety Officer at the time of his retirement from ATCC. The NRC was not notified prior to Dr. Hay's retirement from the ATCC. The ATCC Radiation Safety Committee was still operating under guidance from the ATCC Safety Officer.
- 2) Upon Dr. Hay's retirement, we actively pursued appointing a new Radiation Safety Officer. After reviewing the training and work experience of Dr. Judith Kantor and discussing the current ATCC Radiation Program with her, she accepted the responsibility of the ATCC Radiation Safety Officer. Dr. Kantor began an internal review of the program and an assessment of the future needs of the ATCC in regards to the use of radioisotopes and the gammator. From this review it was determined that the program was currently in compliance, but changes were needed to the ATCC's current Radiation Program to meet the future needs of the company. The Radiation Safety Committee decided that we would rewrite the program and prior to initiating any program changes, we would notify NRC of the appointment of a new RSO, membership changes on the Radiation Safety Committee, changes to the approved users, and modifications to the program contents at the same time. Due to the NRC inspection on November 18, 2004, we immediately provided written notification to the NRC that Dr. Judith Kantor had been designated as Radiation Safety Officer for the company.

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3) An amended license was received from NRC on December 15, 2004 designating Dr. Kantor as the ATCC Radiation Safety Officer. The citation will be discussed with the Radiation Safety Committee, so that all members are aware of the need to notify NRC prior to changes to the RSO position.

4) The amended license was received on December 15, 2004. The ATCC is now in compliance with condition 12 of license No. 45-25425-01.

At the time Dr. Kantor agreed to accept responsibility for the Radiation Safety Program, the only ongoing NRC related activity covered by the ATCC license was use of the sealed-source gamma irradiator. Dr. Kantor was in the process of amending our license in order to identify and include our future work with radioisotopes as well as identifying new scientists and laboratory locations. This application for amending the ATCC license, which will include new users and designated laboratory locations, would have also listed Dr. Kantor as the Radiation Safety Officer.

The delay in getting the amendment filed was due to delays in determining which laboratories would be dedicated for use of radioisotopes under the ATCC's facilities expansion program. We determined that replacement of Dr. Hay with a qualified Radiation Safety Officer was meeting the requirements of our license, and were not aware of a time limit on notification of NRC of this change. We planned the notification to coincide with our requested license amendment.

Sincerely,



Frank P. Simione, V.P.
Management and Compliance Services



Judith A. Kantor, Ph.D.
ATCC Radiation Safety Officer

Cc: Regional Administrator
Region I