

**AUTOIMMUNE** Inc.

128 Spring Street  
Lexington, MA 02173



May 31, 1994

U.S. Nuclear Regulatory Commission  
Attention: Document Control Desk  
Washington, D.C. 20555

RE: **Reply to a Notice of Violation**

Docket No. 030-33074  
030-33209

License No. 20-30017-01  
20-30017-02

Dear Sirs,

Reference is made to the May 23, 1994 Notice of Violation (Severity Level IV) issued to AutoImmune Inc. following the conduct of a routine safety inspection on April 25, 1994 by Ms. Sheri A. Arredondo. The Notice of Violation identified the frequency and schedule of radiation surveys conducted by AutoImmune as two areas which the company needs to address to ensure full compliance with NRC requirements.

In accordance with 10 CFR 2.201, AutoImmune Inc. provides the following responses to the Notice of Violation.

**NRC Observation #1:** Radiation surveys were not made by the user after each experimental run or at the end of the day radioisotopes were used.

- 1) **Rationale:** AutoImmune Inc. had interpreted this radiation monitoring requirement to be applicable to areas in which either higher levels of isotopes or more penetrating radiation sources were employed, as opposed to the low levels of tritium which were used by AutoImmune Inc.
- 2) **Corrective Action:** All scientists have been informed of the need for monitoring the radiation area after each use or at the end of the day in which isotopes have been used. On May 13, 1994, the Radiation Safety Officer emphasized this radiation monitoring requirement during the annual radiation training course for employees using radiation or frequenting areas of radiation use. Scientists are now monitoring after use as required and are recording these assay results in a designated section of the Wipe Test Log Book.

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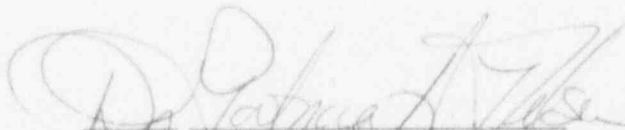
- 3) **Corrective Action Monitoring:** The Radiation Safety Officer will check the use of radioactive materials and experiment dates to verify that scientists are monitoring their areas after use of all radioactive isotopes.
- 4) **Compliance Date:** AutoImmune Inc. is now operating in full compliance with this NRC requirement.

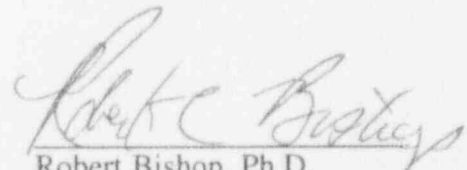
**NRC Observation #2:** The Radiation Safety Officer did not conduct monthly radiation surveys of all laboratory areas.

- 1) **Rationale:** The Radiation Safety Officer was remiss in the conduct of the monthly radiation area surveys. Surveys were conducted on a quarterly basis.
- 2) **Corrective Action:** An NRC authorized user has been assigned to assist the Radiation Safety Officer in the conduct of monthly radiation surveys. Radiation surveys were conducted in April and May of 1994, and will continue to be performed on a monthly basis.
- 3) **Corrective Action Monitoring:** The Radiation Safety Officer and an assistant have been assigned the responsibility for ensuring that the radiation surveys are conducted on a monthly basis.
- 4) **Compliance Date:** AutoImmune Inc. is now operating in full compliance with this NRC requirement.

AutoImmune Inc. welcomes the opportunity to interact with the NRC and is grateful for the guidance provided during the course of the April 25, 1994 NRC safety inspection. Please forward any questions or comments which you may have regarding the contents of this correspondence to Patricia A. Nelson, Ph.D., Radiation Safety Officer at (617)-860-0710.

Sincerely,

  
Patricia A. Nelson, Ph.D.  
Head of Immunology  
Radiation Safety Officer

  
Robert Bishop, Ph.D.  
Chief Executive Officer

cc: Regional Administrator, Region 1