

APPENDIX A

NOTICE OF VIOLATION

AutoImmune, Inc.
Lexington, Massachusetts 02173

Docket No. 030-33074
License No. 20-30017-01

During an NRC inspection conducted on April 25, 1994, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

Condition No. 15 of License No. 20-30017-01 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in an application dated January 22, 1993.

Page 16 of the Radiation Safety Guide contained in the application dated January 22, 1993 requires, in part, that radiation surveys be made by the user after each experimental run or at the end of the day radioisotopes are used, and that the Radiation Safety Officer conduct monthly surveys of all laboratory areas.

Contrary to the above from June 3, 1993 to April 25, 1994, radiation surveys were not made by the user after each experimental run or at the end of the day radioisotopes were used, and the Radiation Safety Officer (RSO) did not conduct monthly surveys of all laboratory areas. Specifically, radioisotope users did not perform radiation surveys after each experimental run or at the end of the day radioisotopes were used. Also, the RSO performed wipe tests on September 21, 1993, December 31, 1993, February 25, 1994, and April 22, 1994, a frequency less than monthly.

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

Pursuant to the provisions of 10 CFR 2.201, AutoImmune, 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. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause 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.

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