

APPENDIX A

NOTICE OF VIOLATION

Fuji ImmunoPharmaceuticals Corporation
Lexington, Massachusetts 02173

Docket No. 030-33051
License No. 20-30013-01

During an NRC inspection conducted on December 7, 1993, 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 15 of License No. 20-30013-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated January 4, 1993.

Page 16 of the licensee's Radiation Safety Manual contained in the application dated January 4, 1993 requires, in part, that radiation surveys be performed by users after each experimental run or at the end of the day radioisotopes are used, and that decontamination and re-surveys must be performed of areas found to exceed 200 disintegrations per minute per 100 centimeters squared for tritium and sulfur-35.

Contrary to the above, from May 1, 1993 through December 7, 1993, radiation surveys were not performed by users after each experimental run or at the end of the day radioisotopes are used. Specifically, the radiation surveys were not adequate in that on a few occasions, decontamination and re-surveys were not performed of areas found to exceed 200 disintegrations per minute per 100 centimeters squared for tritium and sulfur-35.

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

Pursuant to the provisions of 10 CFR 2.201, Fuji ImmunoPharmaceuticals Corporation 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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