

APPENDIX A

NOTICE OF VIOLATION

Department of Health and Human Services
Food and Drug Administration
Winchester Analytical and Engineering Center
109 Holton Street
Winchester, Massachusetts 01890

Docket No. 030-04675
License No. 20-08361-01

As a result of the inspection conducted on July 31, 1990 and August 1, 1990, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1988), the following violation was identified:

10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with all sections of Part 20. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, surveys were not made to assure compliance with 10 CFR 20.106, which limits the yearly average concentration of radioactive material in air discharged to unrestricted areas. Specifically, as of August 1, 1990 the airborne effluent monitoring system indicated a dose rate in millirem per hour and calculations could not be produced to demonstrate that values in 10 CFR 20, Appendix B, Table II had not been exceeded.

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

Pursuant to the provisions of 10 CFR 2.201, Department of Health and Human Services is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.

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