

APPENDIX A

NOTICE OF VIOLATION

Sterling Pharmaceuticals E.S.  
Winthrop Laboratories, Inc.

License No. 52-21076-01

As a result of the inspection conducted on April 28, 1983, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified.

- A. 10 CFR 19.11(a) and (b) require that current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures be posted, or that a notice describing these documents and where they may be examined, be posted.

Contrary to the above, on April 28, 1983, neither the documents nor the notice were posted.

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

- B. Condition 17 of License No. 52-21076-01 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated May 21, 1982, and letter dated July 1, 1982.

1. Your letter, dated July 1, 1982, Item 6, requires that access to the radioactive source area will be supplemented by warning signs.

Contrary to the above, on April 28, 1983, the signs were not posted.

2. Your letter, dated July 1, 1982, Item 8, requires that additional formal training, for the Radiation Safety Officer, will be provided at the source manufacturers facilities.

Contrary to the above, on April 28, 1983, this training had not been provided.

3. Your application dated May 21, 1982, and your letter dated July 1, 1982, states your firm name to be Winthrop Laboratories, Inc.

Contrary to the above, on April 28, 1983, your firm was operating under the name Sterling Pharmaceuticals, E.S.

This is a Severity Level V violation (Supplement VI)

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Sterling Pharmaceuticals E.S.  
Winthrop Laboratories, Inc.

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License No. 52-21076-01

Pursuant to the provisions of 10 CFR 2.201, you are hereby required to submit to this office within thirty days of the date of this Notice, a written statement or explanation in reply, including: (1) admission or denial of the alleged violations; (2) the reasons for the violations if admitted; (3) the corrective steps which have been taken and the results achieved; (4) corrective steps which will be taken to avoid further violations; and (5) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

Date: MAY 26 1983