APPENDIX A

NOTICE OF VIOLATION

Pharmacia, Incorporated
Piscataway, New Jersey 08854

Docket Nos. 030-20664
030-12953
030-12004
License Nos. 29-13915-05
29-13915-04E
29-13915-03G

As a result of the inspection conducted on March 21, 1985, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

A. Condition 15 of License No. 29-13915-05 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated October 26, 1977; a letter dated April 24, 1978; an application dated July 18, 1978; a letter dated January 14, 1982; applications dated January 10, 1983, and June 30, 1983; and a letter dated December 19, 1983.

1. Item 1., in the letter dated December 9, 1983, requires that all personnel survey themselves for radioactive contamination with a survey meter before leaving the laboratory work area.

   Contrary to the above, as of March 21, 1985, personnel in the Reference Lab have not surveyed themselves for radioactive contamination with a survey meter before leaving the laboratory work area.

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

2. Item 2., in the letter dated December 9, 1983, requires that smear tests be conducted weekly in areas where radionuclides other than iodine-125 are used.

   Contrary to the above, as of March 21, 1985, smear tests had not been conducted since November 9, 1984 in the radioisotope room where phosphorus - 32 was used.

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

3. Item 11.a., in the application dated June 30, 1983, requires that survey meters be operable and calibrated every six months.

   Contrary to the above, as of March 21, 1985, a Ludlum Model 3 survey meter (S/N 23646) with a Ludlum Model 44-3 probe (S/N PR 6586) had not been calibrated since September 25, 1983, a period greater than six months. The meter also was not operable due to low battery

power. A Mini-Instruments Minimonitor type 5.10 Model 5-10EB survey meter (S/N 020968) had not been calibrated since January 13, 1984, a period greater than six months.

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

B. 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, as of March 21, 1985, evaluations were not made to assure compliance with 10 CFR 20.303, which limits the disposal of licensed material by release to a sanitary sewerage system. Specifically, no evaluation was made of the releases to the sewerage system in the Reference Laboratory where tens of microcuries of iodine-125 are used.

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

C. 10 CFR 30.51(a) requires that each licensee keep records showing the receipt, transfer, and disposal of licensed material.

Contrary to the above, as of March 21, 1985, the required records of licensed material disposed by release into the sanitary sewerage system from the Reference Laboratory had not been kept.

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

Pursuant to the provisions of 10 CFR 2.201, Pharmacia, Incorporated 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.