NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Pharmatopes, Inc.
Pittsburgh, Pennsylvania 15201

Docket No. 30-15134
License No. 37-18467-01MD
EA 83-10

As a result of the inspection conducted on April 6-7, 1982, and an investigation conducted June 14-16, 1982, it appears that several violations of NRC requirements have occurred. The most significant violation involved falsification of records which are required to be maintained by Pharmatopes' license. Specifically, test records indicated that certain radiation surveys and radioactive contamination wipe tests of packages of incoming material were performed when in fact, the tests had not been performed.

To emphasize the need to maintain complete and accurate records, as required by Pharmatopes' license, and to stress the fact that falsification of records will not be tolerated, the Nuclear Regulatory Commission proposes the imposition of a civil penalty in the amount of $4,000 for this matter. In accordance with the NRC Enforcement Policy (10 CFR Part 2, Appendix C) 47 FR 9987 (March 9, 1982), and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended ("Act"), 42 U.S.C. 2282, PL 96-295, and 10 CFR 2.205, this particular violation and the associated civil penalty are set forth in Section I below:

I. VIOLATION ASSESSED A CIVIL PENALTY

Condition 23 of License No. 37-18467-01MD requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in (1) an application dated February 19, 1979, which includes the licensee's "Safety and Procedure Manual," and (2) a letter from the licensee to the NRC dated May 15, 1979.

Item 10.b.1 of Attachment 2 of this license application dated February 19, 1979 states that incoming packages will be monitored by means of a radiation contamination wipe test of both the inside and the outside of the package, and that the results of the tests will be recorded.

Item 7.A of the letter from the licensee to the NRC dated May 15, 1979 states that incoming packages will be surveyed for radiation at the package surface.

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Contrary to the above, during 1981, records of the results of radiation surveys and radioactive contamination wipe tests were falsified for incoming packages in that not all packages had been surveyed or wipe tested even though the records for these activities indicated that the surveys had been made and the tests performed.

This is a Severity Level III violation (Supplement VII)
(Civil Penalty - $4,000)

II. VIOLATIONS NOT ASSESSED CIVIL PENALTIES

A. Condition 23 of License No. 37-18467-01MD requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in (1) an application dated February 19, 1979, which includes the licensee's "Safety and Procedure Manual," and (2) a letter from the licensee to the NRC dated May 15, 1979.

The licensee's "Safety and Procedure Manual" included with the license application requires that all employees wear film badges at all times during the normal work day.

Contrary to the above, not all employees wore film badges during the normal work day. Specifically, an individual who started work on February 9, 1982 was not issued and did not wear a film badge until February 18, 1982. Also, drivers routinely did not wear film badges on certain trips.

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

B. Condition 10 of License No. 37-18467-01MD limits the use and storage of licensed material to 3402 Butler Street, Pittsburgh, Pennsylvania.

Contrary to the above, licensed material (Technicium 99m) has, on various occasions during 1981 and 1982, been temporarily stored in Whitehall, Pennsylvania.

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

Pursuant to the provisions of 10 CFR 2.201, Pharmatopes, Inc. is hereby required to submit to the Director, Office of Inspection and Enforcement, USNRC, Washington, DC 20555, with a copy to this office, within 30 days of the date of this Notice, a written statement or explanation in reply, including for each alleged violation: (1) admission or denial of the alleged violation; (2) the reasons for the violation, if admitted; (3) the corrective steps that will be taken and the results achieved; (4) the corrective steps that will be taken to

avoid further violations; and (5) the date when full compliance will be achieved. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, Pharmatopes, Inc. may pay the civil penalty in the amount of Four Thousand Dollars or may protest imposition of the civil penalty in whole or in part by a written answer. Should Pharmatopes, Inc. fail to answer within the time specified, the Director, Office of Inspection and Enforcement, will issue an order imposing the civil penalty in the amount proposed above. Should Pharmatopes, Inc. elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, such answer may: (1) deny the violations listed in this Notice in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty. In requesting mitigation of the proposed penalty, the five factors contained in Section IV.B of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. Pharmatopes, Inc.'s attention is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due, which has been subsequently determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282.

FOR THE NUCLEAR REGULATORY COMMISSION

ORIGINAL SIGNED BY:
JAMES M. ALLAN

James M. Allan
Acting Regional Administrator

Dated at King of Prussia, Pennsylvania
this 20th day of May 1983