

Appendix

NOTICE OF VIOLATION

Pharmatopes, Inc.

License No. 12-19333-01MD

As a result of the inspection conducted on October 12-14, 1982, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified:

1. 10 CFR 20.201(b) requires that such surveys be conducted as may be necessary for you to comply with all sections of Part 20.

Contrary to this requirement, you failed to make such surveys as were necessary to assure compliance with 10 CFR 20.106, "Radioactivity in effluents to unrestricted areas." Specifically, no surveys or evaluations were made of the concentrations of radioactive materials in the effluent air discharged from a hood where millicuries quantities of iodine-131 therapy doses were prepared.

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

2. 10 CFR 71.5(a) requires that no licensee shall transport any licensed material outside of the confines of his plant or other place of use unless the licensee complies with the applicable regulations of the Department of Transportation in 49 CFR Parts 170-189.

- a. 49 CFR 173.393(h) states that no significant removable radioactive contamination shall be on the external surface of packages. 49 CFR 173.397 specifies the permissible levels of removable contamination allowed on packages.

Contrary to these requirements, wipe tests were not always performed to ensure that no significant removable radioactive contamination was present on the packages shipped from your pharmacy. Specifically, wipe tests were not performed on shipments of generators returned to Cintichem on August 22, 1980, June 1 and 28, 1980, July 9 and 14, 1982, August 24, 1982, September 20, 1982, and October 8, 1982. Wipe tests were not always performed on the attache cases used to transport doses to area hospitals.

- b. 49 CFR 173.395(a)(1) states that each shipper of a Specification 7A packaging must maintain on file for at least one year after the latest shipment and be prepared to provide the Department, a complete certification and supporting safety analysis demonstrating that the construction methods, packing design, and materials of construction are in compliance with the specification.

Contrary to this requirement, you failed to maintain on file the Specification 7A packaging certification for the packages used to ship generators to Cintichem, and the cardboard containers used to ship doses to area hospitals.

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

3. License Condition No. 23 requires that all licensed material be possessed and used in accordance with statements, representations and procedures contained in application dated March 10, 1980, and letters dated April 15, 1980, May 19, 1980, and May 24, 1980.

License application dated March 10, 1980, states that the procedures described in Appendix D Section 2 will be used for calibration of the dose calibrator.

Appendix D Section 2 states that the dose calibrator is linear and functioning properly when the measured activities are within  $\pm 5\%$  of the calculated activities. Errors greater than  $\pm 5\%$  indicate the need for repair or adjustment of the instrument.

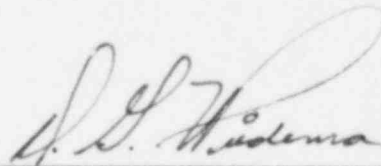
Contrary to this requirement, the linearity checks performed on May 28, 1982, and September 10, 1982, showed a difference of 6% between the measured activity and the calculated activity for dose calibrator No. 1, CRC 10R, Serial No. 10619, and you failed to have the instrument repaired or adjusted.

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

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each item of noncompliance: (1) corrective action taken and the results achieved; (2) corrective action to be taken to avoid further noncompliance; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

11-26-82

Dated



D. G. Wiedeman, Chief  
Materials Radiation Protection  
Section 1