

Appendix

NOTICE OF VIOLATION

Pharmatopes, Inc.

License No. 21-17189-01MD

As a result of the inspection conducted on October 7, 1982, and in accordance with the NRC Enforcement Policy, 47 FR 9987 (March 9, 1982), the following violations were identified:

1. License Condition No. 22 states that the licensee shall possess and use licensed material in accordance with statements, representations and procedures listed in application dated September 8, 1976 and referenced letters.

Item 14.B.3 of this application states that "the entire nuclear pharmacy will undergo a weekly procedure by pharmacy personnel which provides for wipes or smears to be taken from floors, work tables, work instruments, etc."

Contrary to the above, no weekly wipe tests have been performed in the areas used for generator elution, preparation of radiopharmaceuticals from reagent kits and preparation of individual doses since March 19, 1982.

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

2. License Condition No. 22 states that the licensee shall possess and use licensed material in accordance with statements, representations and procedures contained in application dated September 8, 1976 and referenced letters. This application states that radiation monitors, GM meters and your Victoreen "Cutie-Pie" will be calibrated at six month intervals.

Contrary to the above, your radiation detection equipment has routinely been calibrated only annually.

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

This is a repeat item of noncompliance.

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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.

11/1/82  
Dated

D. J. Sreniawski  
D. J. Sreniawski, Chief  
Materials Radiation Protection  
Section 2