

APPENDIX A
NOICE OF VIOLATION

Pharmatopes, Inc.
Washington, D.C. 20016
License No. 08-18308-01MD

Docket No. 30-14826

Based on the results of an NRC inspection conducted on September 13, 1979, it appears that certain of your activities were not conducted in full compliance with NRC regulations and the conditions of your license as indicated below:

- A. 10 CFR 30.41(c), requires that prior to transferring licensed material, you verify that the transferee's license authorizes the receipt of the type, form, and quantity of byproduct material to be transferred.

Contrary to this requirement, as of September 13, 1979, you transferred byproduct material to persons whose license had expired according to your records, without verifying that the licenses had been renewed.

This is an infraction.

- B. Condition 20 of your license requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in your application dated October 5, 1978.

1. Item 15 of this application requires that patient doses containing radioactive material be prepared using lead syringe shields.

Contrary to this requirement, on the day of the inspection, September 13, 1979, personnel preparing radiopharmaceuticals failed to use syringe shields in the preparation of patient doses.

This is an infraction.

2. Item 10 of this application requires that a constancy check be performed and recorded on a daily basis.

Contrary to this requirement, on the dates of August 20 and 21, 1979, the constancy check had not been recorded.

This is a deficiency.

3. Item 10 of this application requires that when the activities measured during linearity tests differ by more than 5% from the calculated activities, the instrument should be adjusted or repaired.

2178 216

Contrary to this requirement, during the March 1979 linearity test, no further action was taken when an assay differed from the calculation by 8%.

This is an infraction.

4. Item 14 of this application requires that packages which have been received, be surveyed for removable contamination using a wipe test.

Contrary to this requirement, as of the date of the inspection, September 13, 1979, packages which were received were not surveyed for removable contamination.

This is an infraction.

5. Item 18 of your application requires that dose shields be surveyed for contamination after they have been returned from the customers.

Contrary to this requirement, on the date of the inspection, September 13, 1979, dose shields which were being returned from customers were not being surveyed for contamination.

This is an infraction.

- C. 10 CFR 20.201(b) requires that you make such surveys as may be necessary 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 20.301, a regulation that describes authorized means of disposing of license material contained in waste. Specifically, on September 13, 1979, you failed to adequately survey for licensed materials on syringe wrappers prior to disposing of the wrappers to the normal trash.

This is an infraction.

2178 217