



# Pharmatopes, Inc.

October 17, 1979

Robert O. McClintock, Chief  
Materials Radiological  
Protection Section  
U.S. Nuclear Regulatory Commission  
631 Park Avenue  
King of Prussia, PA 19406

POOR ORIGINAL

Dear Mr. McClintock:

Subject: Inspection 79-02

This letter is in response to your communication dated September 22, 1979, in which you informed us of certain activities not in full compliance with USNRC Regulations and/or the conditions of our USNRC Materials Handling License, #08-18308-01MD. Corrective measures are outlined below:

- A. With regard to 10CFR 30.41, the accounts in question have been notified by phone and by letter requesting either a new license or letter of timely renewal. All accounts have responded and all licenses are now current. We are in compliance at this time. To avoid further problems of this nature, all licenses will be reviewed at the first of each month. Those due to expire within thirty days from the date review will be notified by phone and letter requesting appropriate action to avoid uninterrupted service.
- B. Application, Condition 20.
1. The intent of item 15 in our license application was to imply that syringe shields would be used in the preparation of radio-pharmaceutical kits from which patient doses are drawn. However, since your interpretation is that shields be used at all times, we will do so, rather than file for a specific amendment to our license. This policy has been in effect since the date of inspection. We are in compliance at this time.
  2. With respect to Item 10, when a linearity test indicates a variation of more than 10%, the test will be repeated, and appropriate action taken if the results of the second test confirm the first test. Full compliance will be observed in all subsequent testing.
  3. Item 10, Constancy Check: As the result of an oversight, the dates on our form for the daily recording of constancy checks were out of sequence. To avoid this problem the forms are now being dated one month in advance, and are checked twice daily. All dates are accounted for with the exception of those mentioned in your letter. We are now in compliance.
  4. Item 14, Package Wipe Testing: Material received on the date in question was not licensed material; however it points out the need

2178 211

8001020

083

to review and revise our method of testing and recording. Up to this point we have been wipe testing the contents of incoming packages and recording the results as '+' or '-' in our isotope inventory log. We will revise this procedure by making a form on which we will record cpm of removable contamination from the package surface and contents, and the result of a G-M survey of the packing material. This should provide adequate data in a form for easy inspection. Full compliance should be achieved by 11-1-79.

5. Item 18, Survey of returned cases: Since the date of inspection, all returned cases are routinely surveyed with a G-M probe. Any evidence of contamination will be reported to the licensee from which the case was received, and appropriate action taken to determine the source of contamination, and to correct the problem. This policy is in effect-we are in compliance at this time.

- C. 10CFR 20.201(b): Since the date of inspection, the trash receptacles near the preparation areas have been added to our daily survey log. Additionally, all items coming in direct contact with the preparation area will be held separately and surveyed before disposal with the daily trash. Any items showing evidence of contamination will be disposed of with the 'hot' trash.

These actions and procedures should be sufficient to ensure compliance. If you have any questions, please call or write.

Sincerely,



Robert F. Irwin, R.Ph.  
Vice President

tdl/RFI

2178 212

ADDENDA:

With reference to our telephone conversation of 10-25-79, Pharmatopes, Inc. is making the following changes in policy regarding the delivery of radio-isotopes:

1. All cases will be surveyed and labelled with the appropriate D.O.T. "Package Label". A daily record of this will be kept for all cases surveyed.
2. The enclosed security fastener will be used as a "security seal." A small hole will be drilled in each half of the attache cases. Each morning prior to delivery, the fastener will be threaded through the holes and locked. Items may not be removed from the case without breaking the fastener, thus ensuring security.

I feel that this system of delivery should resolve any problems we may have had. Should this meet with your approval, I would appreciate written verification of such approval. Should you have any questions, please call.

Sincerely,



Robert F. Irwin, R.Ph.  
Vice President

2178 213