

**Pharmacia  
Diagnostics**

**Pharmacia Diagnostics**  
Division of Pharmacia Inc.  
800 Centennial Avenue  
Piscataway, New Jersey 08854

June 24, 1985

Mr. John D. Kinneman, Chief  
Nuclear Materials Safety Section A  
Nuclear Regulatory Commission  
631 Park Avenue  
King Of Prussia, PA 19406

Dear Mr. Kinneman,

The following actions have been taken with respect to the violations cited as a result of Mr. John McFadden's NRC Inspection No. 85-01:

Violation A

Item 1. The Ludlum Model 3 survey meter (S/N 23646) with a Ludlum 44-3 probe (S/N PR 6585) is now being kept in the Reference Laboratory and all personnel before leaving the laboratory will survey themselves for any radioactive contamination. In the letter you refer to of December 19, 1983, the use of the Geiger Counter for survey of the laboratory personnel was not intended for those working with the iodine-125. However, this intention was not clearly stated.

Item 2. Wipe tests are now being conducted weekly in areas where radionuclides other than iodine-125 are being used and the results are logged.

Item 2a. The Ludlum Model 3 survey meter mentioned above has had its batteries replaced and on April 9 it was reinspected and calibrated at Bio-Med Associates of Kenilworth, New Jersey.

The Mini-Instruments Minimonitor type 5.10 Model 5-10EB survey meter (S/N 020968) has been calibrated with a known amount of phosphorus-32. This meter is used only to survey for contamination with phosphorus-32. A solution containing 0.27 uCi of phosphorus-32 (10,000 disintegrations/second) was spotted onto a piece of plastic-backed absorbent paper and the meter probe was held directly above the spot with the window facing down. The meter read 50/second at 10 cm

8508080082 850722  
REG1 LIC30  
29-13915-05 PDR

and about 150/second at 5 cm. The area of the window is stated by the manufacturer to be 6.4 cm<sup>2</sup>. We will repeat this procedure at six month intervals.

Violation B


Compliance with 10CFR20.303 for iodine-125 requires:

- a. That its chemical form be readily soluble or dispersible in water. The iodinated antibody is in an aqueous solution.
- b.
  1. Appendix D requires that the daily average concentration not exceed  $4 \times 10^5$  uCi/ml (0.152 uCi/gallon). The designated sink for waste disposal delivers about 6 gallons/minute of water; the water is run for a sufficient length of time to accomplish a level below the concentration above.
  2. Appendix C requires the daily total not exceed 10 uCi. This level is not exceeded.
- c. In any one month, the average monthly quantity of water used keeps the quantity of iodine-125 at an average concentration below the value of  $4 \times 10^5$  uCi/ml.
- d. The gross quantity of the iodine-125 released into the sewerage system is very much under the one curie per year.

Violation C

With regard to this item which relates to 10CFR 30.51 (a) an additional column in the iodine-125 log book has now been set-up to record the quantities of this material which is being disposed of through the sanitary sewerage system.

Sincerely yours,



Arnold J. Taft, Ph.D.  
Director, Reference Laboratory

AJT:lb

cc: M. Moliteus  
W. Murphy