U. S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INSPECTION AND ENFORCEMENT

REGION I

Report No. 30-14826/80-01

Docket No. 30-14826

License No. 08-18308-01MD Priority IV Category E

Licensee: Pharmatopes, Inc.
4545 42nd Street, N.W.
Washington, D.C. 20016

Facility Name: Pharmatopes, Incorporated

Inspection At: Washington, D.C.

Inspection Conducted: August 29, 1980

Inspectors: _____ 10-24-80
B. O'Neill, Radiation Specialist date

_____ 10-27-80
J. Johansen, Radiation Specialist date

_____ 10-27-80
F. Costello, Radiation Specialist date

_____ 10-27-80
J. McGinness, Radiation Specialist (Intern) date

Approved by: _____ 10-24-80
J. Kinneman, Chief, Materials Radiological Protection Section, FF&MS Branch date

Inspection Summary:
Inspection on August 29, and September 25,1980 (Report No. 30-14826/80-01)
Areas Inspected: Routine, unannounced, off-shift inspection of radiation protection program including changes in organization; review of previous items of noncompliance; radiation protection procedures; training of personnel; personnel dosimetry records; shipping procedures; transfer of licensed material; radioiodine procedures; laboratory surveys; and receipt of radioactive materials. The inspection involved 27 inspector hours by four NRC regional based inspectors.
Results: Of the nine areas inspected, fifteen apparent items of noncompliance were identified: Infraction - failure to wear personnel monitoring devices -

paragraph 4; Infraction - failure to wear laboratory coats - paragraph 4 and 11B; Infraction - failure to use a syringe shield - paragraph 4; Infraction - failure to monitor hands and clothing when leaving a restricted area - paragraph 4 and 11B; Infraction - failure to perform constancy test on dose calibrator failure to investigate and eliminate high background - paragraph 4; Infraction - individuals not trained in accordance with 10 CFR 19.12 - paragraph 5 and 11B; Infraction - failure to limit exposure to the extremities of an individual - paragraph 6; Infraction - failure to report the overexposure to the NRC - paragraph 6; Infraction - failure to evaluate the exposure at the extremity of an individual - paragraph 6; Infraction - failure to assure compliance with 10 CFR 71.5 - paragraph 7; Infraction - failure to verify recipient's license prior to shipment of material - paragraph 8; Infraction - failure to evaluate personnel exposure to airborne iodine-131 paragraph 11D; Infraction - failure to evaluate iodine-131 concentrations in gaseous effluent - paragraph 11D; Infraction -insufficient sensitivity of wipe testing procedure - paragraph 11E; Deficiency - failure to record surveys of incoming technetium generators - paragraph 11F).

DETAILS

1. Persons Contacted

*A. Tang, Pharmacist and Manager
*M. Vetica, Pharmacist
*R. Irwin, Radiation Safety Officer

The inspectors also interviewed one driver during the inspection.

*Denotes those attending exit interview.

2. Organization

Pharmatopes, Incorporated has facilities in approximately fifteen metropolitan areas. The Corporation's headquarters is located in Oak Park, Michigan. The Washington D. C. radiopharmacy processes radiopharmaceuticals seven (7) days a week for sixty (60) area hospital customers. The Washington, D. C. pharmacy supplies as many as three hundred (300) patient doses daily. This represents a threefold increase in the pharmacy work-load since the last inspection, in September 1979.

Approximately two months prior to the inspection the pharmacist-manager, at the radiopharmacy in Washington D. C. authorized Radiation Safety Officer (RSO), was transferred to the licensee's facility in Toledo, Ohio. The RSO has divided his time between the Washington D. C. and Toledo facilities since his transfer. In addition to the persons listed in Paragraph 1 and the RSO, the Washington D. C. facility employs one secretary, and seven drivers. The manager of the facility is responsible to the Corporation's president who has overall responsibility for management control and radiation safety.

Licensee representatives stated the Corporation is actively engaged in recruiting additional professional staff for the Washington D. C. facility.

3. Review of Previous Items of Noncompliance

The inspectors reviewed the corrective actions taken as a result of inspection 79-02.

A. Failure to verify transferee's license prior to transfer of license material

Recurrent - see paragraph 8 for details.

B.1 Failure to use syringe shields as required

Recurrent - see paragraph 4 for details.

B.2 Failure to record daily dose calibrator constancy checks

The inspectors determined that the licensee failed to perform a constancy check on day of inspection - see paragraph 4 for details.

B.3 Dose calibrator linearity tests indicate difference exceeding license limit (five percent)

Corrected - The inspectors determined by reviewing licensee records and by interviewing licensee personnel that the linearity test has been performed quarterly as required, and that no deviation exceeding five percent of an extrapolated reading was measured.

B.4 Failure to survey incoming packages

Corrected - The inspectors observed that incoming package of radioactive materials were correctly surveyed for radiation exposure rate and wipe tested for removable contamination.

B.5 Failure to survey for contamination the dose shields returned from customers

Corrected - The inspectors observed that the dose shields which had been returned from customers were surveyed for contamination.

C. Failure to conduct surveys to ensure proper disposal of licensed material

Corrected - The inspectors verified by reviewing license records and by interviewing licensee personnel that these surveys are being performed as required.

4. Radiation Protection Procedures

The inspectors arrived at the licensee's facility at 4:30 a.m. on August 29, 1980 and were admitted to the facility by the pharmacist on duty The pharmacist told the inspectors that he was working alone because the driver who normally came early to assist wouldn't be in. The pharmacist went to the dispensing area and continued to dispense the day's technetium-99m compounds. The inspectors observed that the pharmacist was not wearing a film badge or TLD ring badge. When this was brought to his attention, the pharmacist stated that he had left the badges on his desk when he received a phone call earlier. The pharmacist left the restricted area, and returned with his badges.

The finding that the pharmacist was working with radioactive materials and not wearing personnel monitoring devices represents noncompliance with Condition 20 of License Number 08-19308-01MD.

Between 5 and 6 a.m. four drivers arrived and entered the restricted area. One driver surveyed packages of radioactive material which had been delivered to the pharmacy by courier that morning. The others assisted in packaging the attache cases used to transport dispensed materials. The inspectors noted that no individual working in the restricted area was wearing a laboratory coat.

The finding that individuals worked in the restricted area and did not wear laboratory coats represents noncompliance with Condition 20 of License Number 08-18308-01MD. (Also identified in paragraph 11.B)

At approximately 5:45 a.m., the pharmacist eluted a Union Carbide Generator calibrated to contain 16.6 curies molybdenum-99 as of 12 noon August 28, 1980. The eluate contained 12.66 curies of technetium-99m in N50 milliliters of solution. The inspectors observed that the pharmacist withdrew a one milliliter sample from this eluate into a syringe without using a syringe shield.

The finding that the pharmacist withdrew a sample of technetium-99m without using a syringe shield represents noncompliance with Condition 20 of License Number 08-18308-01MD.

Between 5:30 and 7 a.m., drivers left the restricted area to begin delivery of materials to area hospitals. The inspectors observed that no individual monitored his hands or clothing for radioactive contamination before leaving the restricted area. In addition, the inspector observed that the pharmacist left the restricted areas several times without surveying his hands or clothing.

The finding that individuals did not monitor their hands or clothing before leaving the restricted area represents noncompliance with Condition 20 of License Number 08-18308-01MD. (Also identified in paragraph 11.B)

The inspectors observed that the dose calibrator in the Tc 99m dispensing area displayed a background reading which varied from 54 to 85 microcuries. The inspectors observed that this dose calibrator was used to assay the majority of the doses prepared for shipment to hospitals. They pointed out the high background reading to the pharmacist and inquired as to the cause. The pharmacist stated that in the past such readings were due to contaminated vials and needle caps which sometimes fell between the sample chamber and shield. The pharmacist stated that such an occurence was not normally investigated immediately.

The inspectors observed the pharmacist occasionally using a second dose calibrator at a work station separate from the technetium-99m dispensing area. They reviewed the records for the constancy and accuracy tests of both dose calibrators, and determined that no constancy test had been performed on the second dose calibrator.

The findings that one dose calibrator was used on the day of the inspection without a constancy check, and that there had been no investigation of or attempt to eliminate a high background reading on the other dose calibrator represents noncompliance with License Condition 20 of License No. 08-18308-01MD.

5. Training of Personnel

One pharmacist stated that he had worked in Washington, D. C. for approximately three months, and that he had been trained at the licensee's facility in Toledo which operates under a different NRC license. He stated that his radiation safety training at the Washington, D. C. facility had consisted of on-the-job indoctrination by the former manager. When asked by the inspectors to identify the Radiation Safety Officer (RSO) of the D. C. facility, the pharmacist stated the name of an individual who was not the RSO identified in the NRC license. The inspectors asked the pharmacist if he had read the licensee's manual of procedures included with the license application. The pharacist stated that he was familiar with some of the manual, but that he had not read all of its contents and that he was not familiar with all of the procedures submitted to the NRC.

The pharmacist was asked whether he was familiar with the requirement to monitor his hands and clothing each time he left the restricted area. The pharmacist stated he was not aware of this requirement. The pharmacist was asked if he was aware of the requirement that both dose calibrators had to be checked for constancy before use each day and the requirement to investigate and eliminate high background readings. The pharmacist stated he was unaware of the requirement that both calibrators had to be checked for constancy daily and that high background readings must be investigated.

The inspectors asked to review the training records for an employee designated as Employee D in Enclosure A to this report. This Employee no longer works for the licensee. Licensee representatives stated that they could not produce any records of Employee's D training, and stated that they did not know the scope of the training he had received.

The finding that a pharmacist was not familiar with the procedures incorporated as requirements in Condition 20 of License 08-18308-01 MD, and that no record of training was available for Employee D constitute noncompliance with 10 CFR 19.12. Employee D received an exposure to his extremities in excess of regulatory limits (Paragraph 6). (Also identified in paragraph 11.B)

The inspectors discussed his assigned duties with one of the drivers and determined that he had been adequately instructed by the licensee for the duties which he performed.

6. Personnel Dosimetry Records

The inspectors reviewed the licensee's dosimetry records. They noted that for the fourth quarter of 1979, one individual, Employee D (See Enclosure A) had received a hand dose of 20.276 rem. Licensee representatives stated that Employee D had worked for four months at the Washington D.C. They attributed his high exposure to the fact that he was new and slower than an experienced pharmacist.

The TLD ring badge data for Employee D is as follows:

November 5 - December 4, 1979	13.898
December 5 - January 4, 1980	6.387
Fourth Quarter Total	20.276

Licensee representatives stated that no report of this exposure had been submitted to the NRC Office of Inspection and Enforcement or to the individual involved.

The finding of an extremity exposure to Employee D of 20.276 rem represents noncompliance with 10 CFR 20.101(a) which limits extremity dose to 18.75 rem per calendar quarter.

The finding that no report of the exposure was submitted within (30) days to the NRC or to the individual involved, represents noncompliance with 10 CFR 20.405 and 10 CFR 19.13.

The inspectors reviewed TLD badge records and noted that in some instances no readings were given for periods of time during which TLD ring badges had been assigned. (TLD badge information is tabulated in Enclosure A to this report). The inspector noted that not all badges assigned to individuals identified in Enclosure A as Employees A, B, D and E had been returned to the supplier for processing, and that no evaluation of the exposures received during these time periods had been performed by the licensee. Licensee representatives stated that Employees A and E had worked in the restricted area during June and July, 1980, and had eluted generators and dispensed material. Employee E worked full time, while Employee A worked half time in Washington, D.C. and half time in the licensee's facility in Toledo, Ohio. The inspectors noted that no exposure value was reported for either of these individuals for June and July, 1980, and in only one instance had a badge been returned for processing. In addition the records showed that one badge was damaged and could not be read. Licensee representatives stated, no evaluation of the exposure received during this time was made.

The finding that the licensee failed to evaluate extremity exposures received by all individuals working in the restricted area constitutes noncompliance with 10 CFR 20.201(b) with regard to 10 CFR 20.101.

7. Shipping Procedure

The inspectors examined several randomly selected attache cases containing radioactive material which were to be delivered to area customers, and observed licensee shipping activities. All attache cases had been prelabeled according to expected contents, based on customer orders. The inspectors observed that no final survey for radiation levels or removable contamination was performed by the licensee on any shipment container or its contents. The inspectors observed that one attache case in use appeared damaged and that another case did not have a security seal attached before shipment. The inspectors observed that some cases were checked by the licensee to determine agreement of the contents with the labels while others were not.

The finding that the licensee did not monitor each shipment of radioactive material for external radiation and contamination levels, nor to ensure that each package was in an unimpaired physical condition and properly secured, represents noncompliance with 10 CFR 71.5(a) with regard to 49 CFR 173.393(n) (2), (3), and (9).

8. Transfer of Licensed Material

The inspectors reviewed the licensee's records pertaining to the transfer of licensed material. They noted that the licenses of two customers who received radioactive material had expired and that the licensee's files contained no record verifying that these expired licenses were in the process of renewal or had been renewed. Licensee representatives could not find copies of current licenses of the customers and stated that they had no knowledge of license verification for the two customers in question.

The finding that the licensee transfered byproduct material without verifying that the recipient possessed a valid license constitutes noncompliance with 10 CFR 30.41(c).

9. Immediate Action Letter

At 10:30 a.m. on August 29, 1980, the inspectors notified NRC Region I of the number of the apparent items of noncompliance observed and the apparent lack of management control. Based on a telephone conversation between the licensee's President and Mr. F. Costello, Acting Chief, Materials Radiological Protection Section, a letter was sent documenting the immediate steps planned by the licensee to strengthen the management controls and supervision by authorized users at the Washington D.C. facility.

10. Exit Interview

The inspectors met with the licensee representatives denoted in paragraph 1 at the conclusion of the inspection on August 29, 1980. The inspectors summarized the scope and findings of the inspection. The seriousness of the number and nature of the apparent items of noncompliance were discussed and the need for prompt corrective action was emphasized. The inspectors reviewed the enforcement options available to the Commission.

11. September 25, 1980 Inspection

On September 25, 1980 beginning at 5:30 a.m. a continuation of the inspection begun on August 29, 1980, was conducted at the licensee's facility to evaluate the licensee's implementation of the agreements contained in the August 29, 1980 Immediate Action Letter, to observe backshift operations, and to review selected licensee records.

A. Compliance with August 29, 1980 Immediate Action Letter

The inspectors reviewed the steps taken by the licensee to implement the understandings documented in the August 29, 1980 letter.

The inspectors observed that an individual authorized by the license was physically present during all use of licensed material. From review of records and discussions with appropriate personnel, the inspector determined that the authorized Radiation Safety Officer has been working full-time at the Washington, D.C. facility during the month of September.

The inspectors observed that packages containing licensed material were surveyed, packaged and labelled as required prior to shipment.

The inspectors concluded that the licensee had implemented the understandings contained in the August 29, 1980 letter.

B. Radiation Protection Procedures

The inspectors observed routine operations in the nuclear pharmacy. A pharmacist was observed using syringe shields in preparation of kits and dispensing of individual doses. He wore gloves while handling the radioactive materials, but the inspectors observed that he never removed his gloves while he answered the telephone, used a computer terminal and performed other routine tasks. Several drivers, who loaded attache cases with individual doses containing radiopharmaceuticals did not wear lab coats or gloves. The inspectors observed that the drivers picked up the attache cases and left the pharmacy without monitoring their hands for radioactive contamination.

The finding that the drivers did not wear gloves, lab coats or monitor their hands for contamination prior to leaving the pharmacy - a restricted area - represents noncompliance with Condition 20 of License Number 08-18308-01MD. (Also identified in paragraph 4).

The finding that the pharmacist had not been trained to change his gloves while working with nonradioactive materials in order to prevent the spread of contamination contributes to a finding of noncompliance with 10 CFR 19.12. (Also identified in paragraph 4)

Records of Mo-99 breakthrough tests were reviewed in addition to records of the daily constancy checks on one dose calibrator. From these records, it was determined that since September 1, 1980 appropriate Mo-99 breakthrough tests and constancy checks of the dose calibrator have been performed.

The inspectors observed that all personnel in the pharmacy were wearing whole body film badges. In addition the pharmacists wore TLD ring badges while working in the areas where the radiopharmaceuticals were stored and used.

C. Shipping Procedures

The inspectors observed the preparation of packages for shipment and the loading of individual attache cases by a driver. After completion of several cases the driver took a wipe of the inside of the case which was counted for one (1) second in a well counter. Further description of the licensee's counting procedure is contained in paragraph 11.E. Records of each wipe test results were recorded on a chart. The cases were surveyed with a GM meter at the surface and at one meter. Finally a plastic security seal was put in place. The inspectors made independent measurements of the completed cases to assure that they were properly labeled. The inspectors found the cases to be properly labeled, packaged, and secured.

D. Radioiodine Procedures

The inspectors reviewed the procedures for handling radioiodine with the Radiation Safety Officer. They were informed that the licensee routinely receives 50 millicuries of iodine-131 in liquid which is split into 10-20 millicurie iodine therapy doses. Review of the licensee's records indicated that shipments to customers of 10-20 millicurie iodine-131 doses are made several times a week.

The inspectors observed the hood used for the handling of the iodine-131. They were informed that the iodine was handled with the sash of the hood completely opened. The RSO stated that no measurements had been made to determine the linear velocity at the face of the hood. He also stated that no surveys had been made of the concentration of iodine-131 in the hood effluent.

The finding that the licensee failed to evaluate the concentration of iodine-131 in the effluent from the hood used to handle millicurie quantities of iodine-131 represents noncompliance with 10 CFR 20.201(b) with reference to 10 CFR 20.106.

The inspectors reviewed the licensee's records of bioassays for the employees who handled iodine-131 in liquid form. They noted that no thyroid monitoring had been performed for one pharmacist since September 1979, and that no thyroid monitoring of any individual had been performed in 1980. Licensee representatives stated that no other evaluation of personnel exposure to airborne concentrations of iodine-131 had been performed.

The finding that the licensee failed to evaluate the concentration of airborne iodine-131 to which personnel handling millicurie quantities of iodine-131 were exposed constitutes noncompliance with 10 CFR 20.201(b) with respect to 10 CFR 20.103 and Condition 20 of the license which requires monthly bioassays of all individuals who handle iodine-131.

E. Laboratory Surveys

The inspectors reviewed the licensee records of radiation and contamination surveys. They noted that radiation surveys are performed on a daily basis and that contamination surveys are performed weekly.

The inspectors were informed that the standard counting time for wipe samples taken in the facility is six (6) seconds. Samples taken from packages were counted for one (1) second on the day of the inspection. Review of licensee records indicated that the background count for a six second count was approximately 50 counts. The RSO stated that the sodium iodide counting system had not been calibrated for several years.

The inspectors calculated the lower limit of detectability of this system to be approximately 330 counts per minute. (Lower limit of detectability = 4.66 times the square root of the background count rate divided by counting time). Even assuming a counting efficiency of 100%, this exceeds the 100 disintegrations per minute sensitivity limit required by section D.2 of the licensee's "Area Survey Procedures".

The finding that the licensee's method for analyzing wipe tests was not sufficiently sensitive to detect 100 disintegrations per minute constitutes noncompliance with License Condition 20 of License No. 08-18308-01MD.

F. Receipt of Radioactive Materials

The inspectors observed a driver surveying incoming packages. The driver was observed to take GM survey meter readings and a wipe of the external surface of two (2) boxes, one containing Ga-167 and the second containing Xe-133 vials, after he opened the boxes to remove the contents. The inspectors observed that the driver did not wear gloves while handling the radioactive materials. Licensee representatives stated that Mo-99/Tc-99m generators delivered early in the morning were surveyed for contamination and that survey meter readings of radiation levels were performed, but that no records of these surveys were maintained.

The finding that the licensee maintains no records of surveys of incoming generators represents noncompliance with Condition 20 of License Number 08-18308-01MD.

G. Exit Interview

The inspectors met with the Radiation Safety Officer at the conclusion of the inspection on September 25, 1980. The inspectors summarized the scope and additional findings of the inspection.

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ENCLOSURE A

REPORT 30-14826/80-01

PHARMATOPES RING BADGES RESULTS IN MILLIREM

(Data Taken From Vendor Reports)

Badge Start Date	Employee A	Employee B	Employeee C	Employee D	Employee E
4/05/79	4200	5120	4445	-	-
5/05/79	7964	5203	1551	-	-
6/05/79	2543	4063	1099	-	-
7/05/79	5311	3275	1614	-	-
8/05/79	3365	3558	716	-	-
9/05/79	534	1160	604	-	-
10/05/79	5868	1368	229	-	-
11/05/79	9299	(1)	31	13898	-
12/05/79	1969	3973	46	6278	-
1/05/80	0	No badge returned	18	No badge returned	-
2/05/80	774	4033	18	2355	-
3/05/80	33	(1)	Term (4)	Term (4)	-
4/05/80	4202	No badge returned	-	-	-
5/05/80	63	5306	-	-	-
6/05/80	No badge returned (3)	5306	-	-	No badge returned (2)
7/05/80	No badge returned (3)	4751	-	-	0 (2)

(1) According to the TLD vendor who was contacted by telephone on September 2, 1980 by the inspectors, the badge was damaged by heat, moisture or pressure.

(2) Employee E worked full-time during these months, including generator elutions.

(3) Employee A worked intermittently (part-time in Washington, D.C. and Toledo, Ohio) during these months.

(4) Terminated.

APPENDIX A

Summary of Meeting between Region I and
Pharmatopes Incorporated on September 8, 1980

On September 8, 1980 representatives of Pharmatopes, Incorporated and Region I met at the Region I office in King of Prussia, Pennsylvania to discuss the results of the August 29, 1980 inspection.

The items of noncompliance observed during the August 29, 1980 inspection were presented and discussed. Special emphasis was placed on the actions taken as a result of the immediate action letter dated August 29, 1980 and the recurrent item of noncompliance. The NRC representatives expressed their concern regarding the apparent reduction in effectiveness of the licensee's radiation safety program.

The licensee's representative stated that one authorized user who was not on site during the August 29, 1980 inspection had returned on September 1, 1980 to assist in supervision of the licensed activities. This individual is the current Radiation Safety Officer. The licensee representative stated that they had implemented the understandings contained in the immediate action letter. The licensee representative further stated that a new manager had been appointed and would be on site on September 8, 1980; a license amendment to have this person an authorized user would be submitted; an individual at the corporation was in the process of developing an internal audit program but the implementation was 2-3 months off; audio visual training program for drivers was in process; that their packaging for transportation of radioactive material had met 7A classification of DOT; and that a visit was planned to licensing to promptly effect approval of additional authorized users and to get clarification on NRC-DOT regulations.

Enforcement options available to the Commission were reviewed.

APPENDIX B

ATTENDANCE LIST FOR SEPTEMBER 8, 1980 MEETING
BETWEEN NRC AND PHARMATOPES INCORPORATED

For Pharmatopes

Mr. Mark Hebner, President

For NRC, Region I

Mr. James M. Allan, Deputy Director
Mr. Hilbert W. Crocker, Acting Chief, Fuel Facility and Materials Safety Branch
Mr. John D. Kinneman, Chief, Materials Radiological Protection Section

Mr. Barry D. O'Neill, Radiation Specialist
Ms. Jenny M. Johansen, Radiation Specialist