U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 30-11424/81-01

License No. 34-16654-01MD Category E Priority 4

Docket No. 03011424

Licensee: Pharmatopes, Inc.
2208 W. Central Avenue
Toledo, OH 43606

Inspection At: 2208 W. Central Avenue
Toledo, OH

Inspection Conducted: November 3-4, 1981

Inspector: S. R. Lasuk S. R. Lasuk 3/29/82

Approved By: D. J. Sreniawski, Chief D. J. Sreniawski 4/8/82
Materials Radiation Protection
Section No. 2

Inspection Summary:

Inspection on November 3-4, 1981 (Report No. 30-11424/81-01)
Areas Inspected: Special, announced, safety inspection of the licensee's organization; audits; training and instructions to workers; radiological protection procedures; materials, facilities, and equipment; receipt and transfer of material; personnel radiation protection, external and internal; radioactive effluent control and waste disposal; notification and reports; posting of notices; independent measurements.
Results: Of the eleven areas inspected, no items of noncompliance were identified in nine areas; three apparent items of noncompliance (failure to test sealed sources for leakage and/or contamination within six month intervals as required by License Condition No. 14 - Paragraph 6(a); an individual received an extremity dose in excess of the quarterly limit specified in 10 CFR 20.101(a) - Paragraph 8; failure to conduct adequate evaluations as required by 10 CFR 20.201(b) which resulted in extremity doses beyond the quarterly limit specified in 10 CFR 20.101(a) - Paragraph 8) were identified in two areas.

DETAILS

1. Persons Contacted

Monty M. C. Fu, Vice President and Radiation Safety Officer, R.Ph.
Robert F. Irwin, Corporate Radiation Safety Officer, R.Ph.
Robert G. Linger, Authorized User, R.Ph.

2. Organization

Mark T. Hebner is president of this organization and is normally located in Ferndale, Michigan. In addition to Messrs. Fu, Irwin, and Linger, other individuals who work with licensed material include Joe Cesta, a registered pharmacist, Gary Zimmerman, a pharmacist intern, and Don Kou, a technician. This program also includes eight (8) vehicle drivers and seven (7) clerk/typists. As of January 1980, the licensee has employed the services of Nuclear Medicine Associates, Inc., a consulting firm in Cleveland, Ohio.

No items of noncompliance were identified.

3. Audits

NMA, Inc. audits a portion of the licensee's program during each of their visits approximately every two months. Their findings are submitted in a report to the licensee along with recommendations for improving the program. In October 1981, Mr. Irwin conducted an audit of the entire program at this facility using a six-page checkoff list entitled, "Compliance Survey." Plans are to conduct such audits every six months.

No items of noncompliance were identified.

4. Training

The licensee's training program for new hires such as registered pharmacists, graduate pharmacists, and pharmacist interns consists of one month of training at NMA, Inc. in Cleveland, Ohio followed by on-the-job (OTJ) training under the supervision of an authorized user or other individual experienced in the licensee's program.

The OTJ training ranges from three to six months based on the individual's demonstrated work habits and ability. Toward the end of the OTJ training period, the individual is allowed to take over more and more duties but a supervisor is available. The individual is allowed to work alone upon completion of his/her OTJ training.

All employees are required to read the licensee's "Employee Manual" and acknowledge completion of this requirement by signing a form entitled, "Radiation Exposure Control." The manual includes the requirements in 10 CFR 19.12.

An education program for delivery personnel was implemented on September 24, 1981, with a slide/audio presentation. Attendees are given a true/false written examination to test their understanding of the information given in the presentation.

No items of noncompliance were identified.

5. Radiological Protection Procedures

The licensee's basic radiation safety program is described in their Safety and Emergency Procedural Manual, a copy of which was submitted to the NRC in July, 1975. The licensee is committed to the requirements in this manual in addition to those specified in license conditions including a referenced application and six letters.

One license condition (No. 22) requires that survey meters be calibrated at least annually. Records showed that a Victoreen, Model 425, Serial No. 157 lab monitor with GM frisker probe had not been calibrated since October 29, 1980. The inspector was told that this unit is on continuously and used daily for personnel surveys in addition to serving as a lab monitor. Mr. Irwin stated that he was informed by their consultant physicist for their Washington, D.C. facility that this type of instrument was not subject to the calibration requirements for survey meters.

During a subsequent enforcement conference with Messrs. Fu and Irwin in the Region III office on November 18, 1981, the licensee agreed to have NMA, Inc. calibrate this instrument during their next visit and to calibrate this instrument at least annually thereafter.

No items of noncompliance were identified.

6. Materials, Facilities and Equipment

a. Materials

The licensee receives three molybdenum-99/technetium-99m (Mo/Tc) generators each week. On Tuesdays they receive a generator containing approximately 2.25 curies of Mo-99 from New England Nuclear. On Wednesdays and Fridays the licensee receives Union Carbide generators which had been used for one week in their Detroit area facility. When received at this facility, these latter generators each contain approximately 3.65 curies of Mo-99. They have not received any tin-113/indium-113m generators as yet.

Additional byproduct material received each week includes the following: 150 mCi of Xe-133 (15 vials, each with 10 mCi); 50 mCi of I-131 soluion; 1 mCi I-131 hippuran; 50 I-131 caps, each with 100 µCi. Other byproduct material is ordered only as needed.

The licensee's inventory of sealed sources includes a Cs-137 source, No. 208-134-19, containing 217 µCi as of August 1975, and a Ba-133 source, No. 3580479A-25, containing 283 µCi as of April 1979. Leak test records showed that the Cs-137 source was not leak tested from August 1, 1978 to August 8, 1979, and the Ba-133 source was not leak tested from March 29, 1979 to January 7, 1980. This is an item of noncompliance with License Condition 14 which requires that sealed sources be tested for leakage and/or contamination at intervals not to exceed six months. Failure to leak test the Cs-137 source at the required frequency was also an item of noncompliance during the previous inspection of this program on August 8, 1978.

b. Facilities

The licensee's operations are conducted within a one story building with concrete block exterior walls. The east wall is shared with a savings and loan association office and a tailor shop shares the west wall. The licensee has a store front entrance facing Central Avenue which is always locked. All personnel traffic use their side (east) and rear (north) entrances. The side entrance is north of the savings and loan office.

Three rooms which are considered their restricted areas are used for the handling, use, and storage of licensed material. One is their laboratory (or, dispensing room), another is their hot storage area, and the last is their waste decay room. A detailed description of this facility was submitted to the NRC with the licensee's letter dated August 18, 1978.

Operations are conducted from 2:00 a.m. to 5:00 p.m. on weekdays and from 6:00 a.m. to noon on Saturdays. From 2:00 a.m. to approximately 8:00 a.m., only the outer rear door is open. When the facility is unoccupied, all entrances are tied-in electronically to a firm called Certified Alarm who, in turn, contact the Toledo police immediately after receiving an alarm from the facility.

c. Equipment

The licensee uses several portable GM survey meters for direct area and equipment surveys, a lab monitor with GM "frisker" probe for area and personnel contamination surveys, a well counter for evaluation of smears (wipes), a Cutie Pie survey meter for higher levels of radiation if needed, and two Capintec CRC-10R dose calibrators.

They also have air sampling equipment which is in operation when they use an I-131 solution in their hood to prepare therapy doses for customers. Air samples involving charcoal impregnated filter paper are collected inside and outside of the hood; samples are counted and the results recorded.

Five vehicles are used routinely for their deliveries and two additional 4-wheel drive vehicles are available if needed. The licensee currently has about thirty-five customers, mainly hospitals but also some clinics and two doctors. All customers are located within approximately 100 miles of this facility.

One item of noncompliance was identified.

7. Receipt and Transfer of Materials

All incoming packages containing byproduct material are surveyed at the surface and at three feet in addition to a smear survey. Upon removal of the radioactive material, a direct survey is made of the empty package. All survey results plus pertinent information concerning the licensed material are recorded on a form entitled, "Radioactive Shipment Receipt Report."

Customer orders (prepared radiopharmaceuticals) are placed in lead containers and delivered in DOT approved attache-type carrying cases. Unused portions of such orders, plus waste generated by the customer, are returned to the licensee in these carrying cases for disposition. Before leaving this facility, each loaded case is surveyed, both direct and smears, and the results recorded on their "Shipment Survey Record" form. This form also calls for the transportation index and type of label affixed to the case. Returned cases are also surveyed and the results are entered on the same form.

Information concerning each customer's license is entered into a computer by the licensee. The computer prepares labels for each customer order; however, no label will be issued if the customer is unauthorized to receive the byproduct material that was requested.

No items of noncompliance were identified.

8. Personnel Radiation Protection

The film badge services of R. S. Landauer, Jr. and Company are utilized by the licensee on a monthly basis except for three individuals, Messrs. R. Irwin, R. Linger, and J. Cesta, who have been placed on a weekly badge service as of October 26, 1981. All personnel at this facility are issued a body badge and those involved in the laboratory operations also use a finger badge.

In accordance with the requirements in 10 CFR 20.405, the licensee submitted a letter dated October 9, 1981 to Region III in which they reported a third quarter extremity exposure for an employee (A) in excess of the 18.75 rems specified in 10 CFR 20.101(a). During this inspection, it was learned that the licensee received a telegram on August 31, 1981, from Landauer reporting an extremity dose of 13.99 rems for employee "A" for the badge period July 15 through August 14, 1981. Mr. Irwin stated that after they received this telegram, he met with the employee to discuss his radioactive material handling

technique and where he may improve to reduce exposure to his hands. Mr. Irwin then observed employee "A" as he performed his regular duties for a couple of days. After that, he was allowed to continue his work without any direct observation by a more experienced user.

On October 5, 1981, the licensee received another telegram from Landauer reporting an extremity dose of 11.14 rems for the same employee for the badge period August 15 through September 14, 1981. The employee was immediately excused from work involving radioactive material. The finger badge he was wearing on October 5, 1981 was found to be free of contamination and then sent in for "emergency evaluation" by Landauer. This finger badge, which was worn from September 15 to October 5, 1981, showed 100 millirems. Therefore, employee "A's" extremity dose for the third quarter of 1981 totaled approximately 25 rems. This is an item of noncompliance with 10 CFR 20.101(a) which limits the quarterly extremity dose to an individual in a restricted area to 18.75 rems. The licensee's third quarter badge period ends on October 14. As of October 15, 1981, employee "A" was allowed to resume his regular duties.

He was hired on January 14, 1981 and began working with licensed material on February 17, 1981. His exposure record shows the following extremity exposures prior to July 15, 1981:

February 15 through March 14, 1981	-- 4.89 rems
March 15 through April 14, 1981	-- 5.22 rems
April 15 through May 14, 1981	-- 7.49 rems
May 15 through June 14, 1981	-- 3.51 rems
June 15 through July 14, 1981	-- 3.39 rems

The inspector was told that another employee, who worked with employee "A" on the 2:00 a.m. to 10:30 a.m. shift, left this facility on April 15, 1981. For the period May 15, 1981 to July 14, 1981, the licensee employed summer interns who assisted employee "A" with the laboratory work.

In reviewing exposure records from September 15, 1978 to October 14, 1981, it was found that a second person (employee "B") received an extremity dose of 20.73 rems during the second quarter of 1979. The inspector was informed that this was not a valid exposure. Employee "B" allegedly was leaving his finger badge with his timecard, when not in use. The timecard area was just outside the laboratory and radiation emanating from laboratory operations contributed to the reported exposure for that badge. This was the explanation offered by Mr. Fu after he contacted two individuals during the course of this inspection. One was Alfred T. Gall, former Chief Pharmacist for this facility, who now works for Retail Pharmacy in Fremont, Ohio; the other was employee "B" who is currently employed at another Pharmatopes facility. Mr. Fu stated that Mr. Gall prepared a report concerning this matter which was sent to the NRC and that employee "B" claimed

he saw the report. However, Region III files do not contain such a report and the licensee was unable to produce a copy of the report during this inspection. The inspector subsequently contacted the Materials Licensing Branch in headquarters but they were unable to find any information on this matter in their files.

During the enforcement conference on November 18, 1981, Mr. Fu stated that he was unable to find any more information concerning the reported employee "B" extremity overexposure.

Based on the above information regarding extremity exposures, the licensee is in noncompliance with 10 CFR 20.201(b) for failure to adequately evaluate a higher than usual exposure which eventually resulted in an extremity dose in excess of the quarterly limit specified in 10 CFR 20.101(a). When the licensee received the August 31, 1981 notification from Landauer, they were approximately two weeks into the next badge period. An adequate evaluation would have determined whether or not the individual's exposure was near the quarterly limit; he could have been removed from work with licensed material at that time and possibly avoided the overexposure.

The licensee also failed to adequately show the reported 20.73 rems extremity dose for the second quarter of 1979 was not a valid exposure to an individual. Therefore, this matter also indicates that they are in noncompliance with 10 CFR 20.101(a) which limits the quarterly extremity dose to an individual in a restricted area to 18.75 rems.

The licensee also has 0-200 mR pocket dosimeters and audible alarm dosimeters which are issued to visitors or new hires during their training period.

The Mo/Tc generators used during a given week are maintained in a lead-lined cabinet in the laboratory to minimize the radiation field in this area. Syringe shields, lead containers, lead shield with viewing window, plus plastic gloves and lab coats are used in the licensee's operations in their attempts to minimize exposures and personnel contamination.

Direct radiation surveys are conducted throughout the licensee's facility on a daily basis; these surveys are made after customer's orders have been completed. Smear surveys are also performed throughout the facility on a weekly basis. All area survey results are recorded. A selective review of these survey records showed no unusual radiation fields or contamination levels.

The licensee's bioassay program involves only those individuals who dispense I-131. A sodium-iodide crystal and single channel analyzer is used to determine thyroid counts. A review of bioassay records since the last inspection revealed all thyroid counts were at, or only slightly above, background levels.

Two items of noncompliance were identified.

9. Effluent Control and Waste Disposal

No shipments of waste, destined for a burial site, have been made since the previous inspection and none are planned for the near future. All waste generated by the licensee plus that which they bring back from customer facilities is placed in shielded containers marked, "short lived," "medium-lived," "long-lived," and "x-long lived" for decay. This waste is held until a radiation survey shows it is at background levels and then it is discarded as normal trash; survey results are recorded. They do not dispose of any waste into the sewer system.

Containers of Xe-133 are maintained in their fume hood until needed for customer use.

During the handling of I-131 solutions in their fume hood, air samples are collected within and outside the hood, at approximately head height. They calculate the airborne I-131 concentration for the restricted (laboratory) area and the unrestricted (hood/stack exhaust) area and compare it to the limits specified in 10 CFR Part 20, Appendix B, Tables I and II. All such samples collected through October 1981 showed no airborne concentrations in excess of these limits.

No items of noncompliance were identified.

10. Notification and Reports

The licensee sent a letter dated April 8, 1981, to Region III reporting a diagnostic misadministration during the first quarter of 1981 as required by 10 CFR 35.43. The misadministration which occurred on March 26, 1981, was due to a licensee representative placing a radiopharmaceutical in a vial which was different from the radiopharmaceutical specified on the label. The responsible individual was terminated before the end of March 1981. The inspector was informed that the reading of labels is stressed during an individual's formal training and internship in pharmacy.

During this inspection, it was learned that another diagnostic misadministration occurred at a hospital near Toledo, Ohio on October 9, 1981, due to a similar licensee error. A female patient was given what was specified as 5.8 mCi Tc-99m labeled MAA for a lung scan. However, no lung uptake was obtained and distribution of the activity was found in the liver, spleen, and bone marrows. Later, the radiopharmaceutical was found to be sulfur colloid. This matter was reported to the licensee by the doctor who is director of the nuclear medicine department at the hospital.

Mr. Irwin stated that this is another case where the individual failed to read the label. He plans to submit his report on this matter at the end of the calendar quarter.

The personnel monitoring reports for 1978 and 1979 as specified in 10 CFR 20.407 were submitted to the NRC according to Messrs. Fu and Irwin. They were unable to produce a copy of the information that was submitted for 1978; however, a copy of their 1979 report was shown as being submitted with their letter dated March 12, 1980.

No items of noncompliance were identified.

11. Posting of Notices

Form NRC-3, "Notice to Employees" plus the notice specified in 10 CFR 19.11(b) was posted on a bulletin board in the packaging area, just outside the laboratory.

No items of noncompliance were identified.

12. Independent Measurements

Direct radiation level measurements were made by the inspector using Region III's Xetex meter, Model 305B, NRC No. 008366, calibrated on September 24, 1981, and the licensee's Victoreen 491 meter, Serial No. 1963, calibrated by the manufacturer on June 26, 1981. Maximum readings at the front of the open cabinet containing their current Mo/Tc generators was 2.2 mR/hr with the Region III meter and 2.1 mR/hr using the licensee's meter. No unusual levels of radiation were found in other areas of the laboratory. Surveys in the waste storage areas showed maximum readings at the top surface of the container holding medium-lived waste; results were 80 mR/hr with the Region III meter and 95 mR/hr with the licensee's meter.

No items of noncompliance were identified.

13. Exit interview

The inspector met with Messrs. Fu and Irwin at the conclusion of this special inspection on November 4, 1981 and summarized the findings noted in the body of this report. The three items of noncompliance were discussed as well as the calibration of the lab monitor with frisker probe. In regard to the reported employee "B" extremity overexposure, Mr. Fu stated that he would continue with his attempts to obtain information concerning the evaluation of that matter. The licensee was advised of the probability of a civil penalty as a result of the employee "A" extremity overexposure and that licensee management may be asked to attend a meeting in the Region III office to discuss this and other matters pertinent to the inspection findings.

14. Enforcement Conference

A meeting was held with licensee representatives in the Region III office on November 18, 1981 to discuss the inspection findings, the

licensee's corrective actions, and NRC enforcement options. Those in attendance were Monty M. C. Fu and Robert F. Irwin of the licensee's organization plus A. Bert Davis, C. E. Norelius, L. R. Greger, D. G. Wiedeman, W. H. Schultz, and S. R. Lasuk of the Region III office. The three items of noncompliance and the lab monitor calibration requirements were discussed during this meeting and are addressed in the body of this report. No new information was provided by the licensee to change the inspection findings.

ATTACHMENTS: Identification
of Individuals

Attachment

Employee A - Robert Linger
Employee B - T. H. Sing