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

REGION III

Report No. 30-12332/80-01

Docket No. 30-12332 License No. 21-17189-01MD

Licensee: Pharmatopes, Incorporated
25721 Coolidge
Oak Park, MI 48237

Investigation At: Oak Park, MI, and Detroit, MI

Period of Investigation: September 24-26 and October 2-3, 1980

Investigator: _____ 3/12/81
J. B. McCarten Date

Inspector: _____ 3/12/81
D. G. Wiedeman Date

Reviewed By: _____ 3/12/81
J. F. Streeter, Acting Director Date
Enforcement and Investigation Staff

_____ 3/12/81
D. J. Sreniawski, Acting Chief Date
Materials Radiation Protection
Section 2

Investigation Summary

Investigation on September 24-26 and October 2-3, 1980 (Report No. 30-12332/80-01)

Areas Investigated: Investigation was conducted after the licensee reported a driver lost a package containing 100 millicuries of technetium-99m which was later found along a roadway near a Detroit hospital. An inspection of the licensee's entire radiation safety program was also conducted concurrently with the investigation. The investigation/inspection consisted of a review of pertinent records and procedures, and interviews of personnel. The investigation/inspection involved twenty-eight man hours on site by two NRC representatives.

Results: It was determined that on July 29, 1980, a licensee driver, who was delivering technetium-99m to Detroit Central Hospital, removed the container from a brief case and subsequently lost immediate control of the isotope. This resulted in the container falling from the delivery vehicle, breaking on impact, and contaminating an adjacent roadway and curb area. The damaged container was found several hours later. One member of the public was slightly contaminated during the recovery effort. The Michigan Department of Public Health decontaminated the individual and the adjacent roadway. Nine items of noncompliance were identified: (1) 10 CFR 71.5(a), failure to block or brace packages being transported (Paragraph 4); (2) License Condition 22, failure to properly perform dose calibrator calibration checks (Paragraph 6); (3) License Condition 22, failure to perform bioassays (Paragraph 7); (4) License Condition 22, failure to perform leak tests of sealed sources (Paragraph 9); (5) License Condition 22, failure to calibrate survey instruments (Paragraph 8); (6) 10 CFR 71.5(a), failure to use security seals on packages containing radioactive materials (Paragraph 5); (7) 10 CFR 71.5(a), failure to utilize package that had undergone Department of Transportation Certification and Safety Analysis test (Paragraph 5); (8) 10 CFR 71.5(a), failure to maintain shipping papers on packages used to transport radioactive materials (Paragraph 5); (9) 10 CFR 20.203(f)(4), failure to remove radioactive labels from discarded containers (Paragraph 10).

REASON FOR INVESTIGATION

Investigation was initiated following the licensee's report on July 29, 1980, of a lost radiopharmaceutical.

SUMMARY OF FACTS

The licensee reported that on July 29, 1980, a driver lost a package containing 100 millicurie dose of technetium-99m during a delivery to Detroit Central Hospital. The Michigan Department of Public Health, Division of Radiological Health, responded to the hospital, and after a search of the area, recovered the container which had shattered on a roadway near the hospital. During the search effort one member of the public was slightly contaminated. Both the individual and the roadway area were decontaminated by state personnel.

The driver had removed the container from its carrying case while attempting to make the delivery in an effort to impress the security guard with the importance of the delivery, so that he would allow access to the hospital's Nuclear Medicine Department which was closed at the time. The driver failed to return the container to it's carrying case (brief case), placed the container on the bumper of the delivery vehicle and, inadvertently, drove off with it still on the bumper. The container fell off the bumper, apparently shattered on impact or was run over by another vehicle. The driver realized the mistake while enroute to the next delivery point. After making that delivery, the driver returned to Detroit Central Hospital searched for the lost package but did not find it. Although the delivery vehicle was equipped with a mobile radiotelephone, the driver did not report the loss until returning to the licensee's facility at 2:45 p.m.

Upon notification of the loss, the licensee's Radiation Safety Officer called the Nuclear Regulatory Commission and contacted the state authorities who attempted to locate the lost package. Licensee representatives did not respond to the incident until the package had been found by state authorities.

The licensee also stated that due to procurement problems, the required security seals and leather security strap for the brief case had not been used and this may have contributed to the driver's loss of control of the material in this incident.

Both an investigation of the incident and an inspection of the licensee's radiation safety program were conducted concurrently. Nine items of noncompliance with NRC requirements were identified; four of these related to the improper packaging and shipping of radiopharmaceuticals, and the remaining five items related to license requirements for the safe handling and use of materials at the licensee's facility.

DETAILS

1. Persons Contacted

Pharmatopes, Incorporated

Mark T. Hebner, President
C. Ann Smith, Radiation Safety Officer
Individual "A"
Individual "B"

Thomas Dykstra, Health Physicist, State of Michigan, Department of Public Health, Division of Radiological Health

2. Interview of the State of Michigan Department of Public Health Personnel

On October 3, 1980, Thomas Dykstra, Michigan Department of Public Health, Division of Radiological Health, was interviewed and stated that on July 29, 1980, at about 4:20 p.m., he was notified by the state emergency response coordinator that the NRC had been notified by the licensee that 100 millicuries of technetium-99m had been lost by a driver in the vicinity of Detroit Central Hospital, Detroit, Michigan.

Dykstra stated that following this notification he called both the Detroit Police Department and the hospital administrator, and neither were aware of the incident. Dykstra said he proceeded to the hospital and arrived at 7:02 p.m. After briefing Individual B, a hospital representative, he and Individual B began a search of the area along the probable avenues the driver would have used when entering and exiting the hospital area. A short time into the search, Individual B informed him that she had located the package along a curb on the Northeast corner of 3rd Avenue and Virginia Park. The container was shattered and when Individual B picked up a fragment, she received slight contamination to her hands (1200 CPM) and feet (600 CPM). Dykstra stated Individual B was immediately decontaminated by him at the scene.

Dykstra said he observed fragments of the outer container on the street, and a glass fragment from the inner container on the grass along the curb. He said he surveyed the area and found contamination of 1200 counts per minute on the street and grass.

Dykstra stated additional Department of Public Health personnel then arrived, and the Detroit police were notified, however, the police did not arrive until ninety minutes after the initial call at which time the roadway was sealed off and the contaminated dirt was removed by Department of Public Health personnel. He stated the Detroit Fire

Department subsequently washed down the entire area which was then surveyed showing background level. The decontamination process was completed at about 0100 hours on July 30, 1980. A sketch of the area, drawn by Dykstra, is appended to this report as Attachment 1.

3. Interview of Radiation Safety Officer

On October 2, 1980, C. Ann Smith, R. Ph., M.S., was interviewed and stated on July 29, 1980, Individual A, a Pharmatopes driver, was delivering a 100 millicurie dose of technetium-99m to Detroit Central Hospital, Detroit, Michigan, and lost the dose after removing it from a brief case and placing it on the rear bumper of her automobile. Smith stated Individual A had been unable to deliver the material to the hospital's Nuclear Medicine Department because the Department was closed at the time she arrived at the hospital. The driver, after a conversation with a hospital security guard, refused to leave the dose with the guard. Smith said during this conversation, the driver removed the dose container from the carrying case, obstensibly to impress the guard with the importance of her job, in order to gain admission to the Nuclear Medicine Department. The guard, however, again refused to let her enter. Smith stated Individual A then left the hospital, placed the container on the bumper of her delivery vehicle, placed the carrying cases in the vehicle, and apparently drove off with the container still on the bumper of the car. The container apparently fell off the bumper of the car onto the street, a short distance from the hospital. She said the dose container was either damaged on impact or was run over by another vehicle.

Smith stated the driver realized she had lost the container dose and returned to the hospital at about 1:45 p.m. to search for it. She said the driver's vehicle was equipped with a radiotelephone, yet the driver failed to notify the licensee of the incident until her return to the pharmacy about 2:45 p.m.

Smith stated Individual A was very distraught when reporting the incident and at that time quit her job, leaving the pharmacy abruptly when questioned about the circumstances surrounding the loss of the material. Smith advised she called both the Detroit police and the hospital police informing them of the incident. She then notified the NRC, who advised her to call the local news media and warn the public about the lost material, which she did. Shortly after this call, the Michigan Department of Public Health contacted her and she provided them with all the available information she had concerning the incident. Smith also stated, due to a lack of manpower in the laboratory (herself, one driver and one pharmacist), she was unable to dispatch any licensee personnel to the hospital to assist in the search efforts.

Smith said that at about 7:00 p.m., the Michigan Department of Public Health notified her that the package had been found shattered at the

northeast corner of 3rd Avenue and Virginia Park, a short distance from Detroit Central Hospital. She said she proceeded to the hospital and arrived at 10:30 p.m., at which time the Michigan Department of Public Health and local emergency services personnel were removing the container and contaminated material from the area. Smith said at this time, she learned that one member of the public, Individual B, had been slightly contaminated when she entered the contaminated area and picked up a piece of the damaged container. Smith advised Individual B was decontaminated by Michigan Department of Public Health personnel at the scene. A report of the incident, authored by Smith, is attached to this report as Attachment 2.

4. Interview of Individual A

On October 3, 1980, Individual A, former driver, Pharmatopes, Inc., was interviewed and stated she had been employed with the licensee from June 1980, until July 29, 1980. Individual A said on July 29, 1980, at about 10:30 a.m. she left the licensee's pharmacy for the first of four deliveries to hospitals in the Detroit area, the first stop being Detroit Central Hospital. She said she became lost in traffic enroute and arrived at the hosptial at 12:15 p.m., at which time she was informed by the hospital security guard that the Nuclear Medicine Department was closed. She tried to page the nuclear medicine technician's through the security guard. However, these attempts were unsuccessful and the guard refused to allow her access to the department to drop off the radiopharmaceuticals. Individual A said at this time she felt the guard was not aware of the importance of the proper delivery of the radiopharmaceuticals in question, so she opened the brief case and removed the container which was labeled "Radioactive" and held the dose up to the guard. He again declined to allow her access to the department. Individual A said at this point she became distraught over her inability to deliver the material and hurriedly gathered up the brief case from which she had removed the container and gathered up another empty brief case which was in the security office. She said she took both suitcases and the dose container to the rear of the vehicle, placed the dose on the rear bumper of the car, took the two brief cases and placed them in the car, and then drove off. Individual A stated while enroute to her next hospital, Woodward Nuclear Clinic, she realized she had left the container on the bumper. She made her delivery and returned to Detroit Central Hospital at about 1:45 p.m. to search for the missing package. She said she checked with the security personnel at the hospital to see if anyone had found the dose or container. However, it had not been recovered.

License Condition 16 states the licensee may transport licensed material in accordance with the provisions Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material." 10 CFR 71.5 required licensees who transport licensed material to comply with applicable requirements of

the regulations of the Department of Transportation in 49 CFR Parts 170-189. 49 CFR 177.842(d), "Radioactive Material," states in part, "Packages must be blocked and braced, that they cannot change positions during conditions normally incident to transportation."

Contrary to the above requirements, the 100 millicurie dose of technetium-99m transported by Pharmatopes, Inc., of Oak Park, Michigan, was neither blocked or braced in a manner which would preclude its changing position during transportation on July 29, 1980, in that the technetium-99m package was left unsecured on the bumper of the delivery vehicle. This resulted in the loss of the package and to radioactive contamination of public property and to one individual.

Individual A also stated she did not contact Pharmatopes Laboratory via the mobile radiotelephone to inform them of the situation even though she realized from her training this was the proper procedure. She returned to Pharmatopes at about 2:45 p.m. and informed the dispatcher about the lost container, who in turn informed the RSO, Ann Smith. The RSO asked her to return to the hospital to search for the container. She said at this time she told Smith she quit, and left the building.

Individual A said she realized from good common sense she should have called the office. However, in the past, she felt intimidated by the dispatcher's tone on the radio and, therefore, decided not to report the incident. She stated she received training in radiation safety and how to handle radioactive spills, but never received specific training instructions on how to handle accident situations, other than to call in on the mobile radiotelephone.

5. Interview of Pharmatopes President

On October 3, 1980, Mark Hebner, President, Pharmatopes, Inc., was interviewed. Hebner stated he was not present in the laboratory on the day of the incident. He said it was later reported to him that the driver had apparently removed a dose container from its carrying case, (a Samonsite brief case), placed on the rear bumper of her delivery vehicle, and drove off. The container apparently fell off the bumper in the vicinity of the hospital. He said the driver realized shortly afterwards she had lost the container but failed to immediately return to the hospital to search for it, and also failed to immediately report the incident to her supervisor.

He stated all drivers have received training in radiation safety and emergency procedures which included specific instructions to the drivers that if they encounter a problem they are to immediately notify the dispatcher via the mobile radiotelephone. He stated in this instance the driver failed to do this, resulting in a delayed response by Pharmatopes management to the incident.

Hebner also stated the material was packaged in a glass vial which was in a four-inch New England Nuclear (NEN) lead and steel encased holder with a screw-on cap. This holder was placed in a Samonsite brief case commonly used by Pharmatopes in the delivery of radiopharmaceuticals to its client hospitals. He said the brief case was not sealed with a security seal or leather strap as described to the NRC in the Pharmatopes license application as the method by which Pharmatopes would transport radioactive material. He attributed this condition to his failure to purchase the security seals. He also stated leather straps depicted in the test package which was certified as Specification 7A of the Department of Transportation by Monsanto Laboratory were on order, but had not yet been received. Hebner, when asked if the New England Nuclear radioisotope container has also been certified to DOT standards by Monsanto, along with the test package, responded the NC-808 and NC-804 thirteen-inch lead and plastic dose containers had been certified; however, the four-inch New England Nuclear lead container was not certified. He said he was unaware a test was required in this instance, but if required, one would be administered to certify the four-inch New England Nuclear container for use with the standard Pharmatopes package.

License Condition 16 states the licensee may transport licensed material in accordance with the provisions Title 10, Code of Federal Regulations, Part 71, "Packaging of Radioactive Material for Transport and Transportation Material Under Certain Conditions." 10 CFR 71.5 requires licensees who transport licensed material to comply with applicable requirements of the regulations, appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170-189. 49 CFR 173.393(b) requires in part, that each package must incorporate a feature such as seal, which is not readily breakable and which, while intact, will be evidence that the package has not been illicitly opened. Contrary to the above, on July 29, 1980, packages being transported (delivered) from Pharmatopes, Oak Park, Michigan, to Detroit Central Hospital did not have a security seal feature or leather strap affixed to the package.

The licensee is also in noncompliance with 49 CFR 173.395(a)(1) which requires in part, that each shipper of Specification 7A packaging maintain certification and safety analysis demonstrating that the container meets Specification 7A.

Contrary to the above, the licensee did not have certification and safety analysis for the four-inch NEN dose container for use with the standard Pharmatopes package.

Also, 49 CFR 172.202 states, in part, "Each person who offers a hazardous material for transportation shall describe the hazardous material on the shipping paper in the manner required by this section." 49 CFR 172.203(d) sets forth additional requirements including information, such as description, weight and quantity of material, required

on shipping papers. Contrary to the above, packages being transported (delivered) by the licensee from Oak Park, Michigan, to customers did not have shipping papers.

6. Review of Dose Calibrator Calibration Records

On September 24, 1980, the dose calibrator constancy and linearity check log was reviewed. During this review, it was noted the licensee did not maintain a record of the annual linearity check for 1980, nor was there any record of an annual accuracy check performed by the licensee's consultant, Paul Early & Associates, on June 2, 1980. A review of the consultant's report showed, that these calibrations had been performed. This report, however, did not provide sufficient information from which a determination could be made whether the instrument was calibrated to within plus or minus five percent as required by the licensee's procedures.

In addition, the annual accuracy test performed on June 6, 1977, and on January 11, 1978, showed a fluctuation of nine percent when measuring Co-57. In June 1979, the test showed fluctuations of 10.9 percent when measuring Co-60, and a fluctuation of nine percent for Co-57. These fluctuations were greater than five percent, yet the dose calibrator was not adjusted or repaired after these tests, as required by the licensee's procedures.

Also, this review showed quarterly constancy checks on commonly used radionuclide settings had not been conducted since the inception of this requirement on October 15, 1976. It was also noted a daily dose calibrator constancy check had not been made on the date of this record review, September 24, 1980, yet doses had been drawn that day. During the review of this record, the RSO stated the daily constancy check is done on a daily basis when the pharmacist decides to do it. The RSO agreed, however, that the licensee's procedures require that the check be made prior to drawing doses for the day.

License Condition 22 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated September 8, 1976, which states in Item No. 11, Attachment No. 5, the following tests will be performed on the dose calibrator at the times specified.

a. daily constancy checks
b. annual linearity checks
c. annual accuracy checks
d. quarterly tests on commonly used radionuclide settings

Item H of the above referenced application, states calibration checks which do not agree within plus or minus five percent indicate that the instrument should be repaired or adjusted and a log will be kept of these calibration checks. The information set forth in the previous paragraph demonstrates noncompliance with these requirements.

7. Review of Bioassay Records

On September 24, 1980, the licensee's bioassay records were reviewed. During this review it was determined that five personnel listed below are required to undergo weekly bioassays, in that they routinely handle high levels of I-131 and intermediate levels of Tc-99m.

Ann Smith, R. Ph.
Ashok Shaw, ARRT
John Alexander, ARRT
Garry Brown, R. Ph. (since July 1980)
Michael Grawburg, R. Ph.

During this review, it was found that from December 17, 1979, to January 16, 1980, only two of the four individuals routinely handling high levels of I-131 (100 mCi to 10 Ci) received thyroid bioassays. It was also noted that from May 2, 1980 to May 30, 1980, only two out of the five individuals handling I-131 received thyroid bioassays. On May 12, 1980, only Ashok Shaw received a bioassay and on May 30, 1980, only Ashok Shaw and Michael Grawburg received bioassays.

It was also determined that thyroid bioassays of individuals handling intermediate levels (10 mCi to 1 Ci) of technetium-99m were not performed on the persons drawing doses of these quantities since the inception of this requirement on October 15, 1976.

Therefore, the licensee is in noncompliance with License Condition 22 which requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in an application dated September 8, 1976, which states in Item 12, Attachment 6-B that bioassay procedures will be performed within one week following single operations involving high level quantities of radionuclides and at weekly intervals for continuing operations for individuals handling high levels of iodine-131. For individuals handling intermediate levels of technetium-99m and iodine-131, bioassay procedures will be performed every six months.

8. Review of Survey Instrument Calibration Records

On September 24, 1980, semiannual instrument calibration records were reviewed for the period January 11, 1978 to the present. The survey instruments themselves were checked to assure they were operable.

It was determined Victoreen Model 493, Serial Number 650, survey instrument was calibrated during June 1977, April 1978, and January 1980, the intervals between these dates exceeds six months. Victoreen Model 491, Serial Number 881, survey instrument was last calibrated in June 1977. Victoreen Model 740F, Serial Number 1762 survey instrument was calibrated during June 1977 and April 1980, an interval exceeding six months. Victoreen Frisker, Serial Number 339, was last calibrated in February 1978.

Therefore, the licensee is in noncompliance with License Condition 22 which requires licensed materials be possessed and used in accordance with the statements, representations, and procedures contained in the application dated September 8, 1976. This application states in Item 11, Attachment 5-C, that radiation survey instruments will be calibrated at six month intervals.

9. Review of Sealed Source Leak Test Records

On September 24, 1980, the leak test records were reviewed to determine if the semiannual leak tests of sealed sources for contamination had been conducted. It was determined during this review that a 201 microcurie cesium-137 sealed calibration source, Serial Number 231-141-15, was not leak tested from January 11, 1978 to January 15, 1980.

Therefore, the licensee is in noncompliance with License Condition 22 which requires licensed material be possessed and used in accordance with the statements, representations, and procedures contained in the application dated September 8, 1976. This application states in Item 14, Attachment 8-0(i), that each sealed source containing byproduct material will be tested for leakage and/or contamination at intervals not to exceed six months.

10. Examination of Waste Disposal Area

On September 24, 1980, an examination was conducted of the waste disposal area at the Pharmatopes facility. During this examination, empty uncontaminated containers were found in a trash bin with radioactive labels still affixed to the containers.

Therefore, the licensee is in noncompliance with 10 CFR 20.203(f)(4) which requires that licensees shall, prior to disposal of an empty uncontaminated container to unrestricted areas, remove or deface the radioactive material label.

11. Exit Meeting

On October 3, 1980, an exit meeting was held at the conclusion of the investigation with the licensee representatives. The scope and findings of the investigation were summarized and management was informed of the items of noncompliance and enforcement options available to the Commission. Management was advised that escalated enforcement action was being considered in this case.

Attachments:
1. Sketch of contaminated area
2. Ltr dtd 7/31/80 Pharmatopes, Inc. to NRC

GENERAL ACTIVITY REPORT

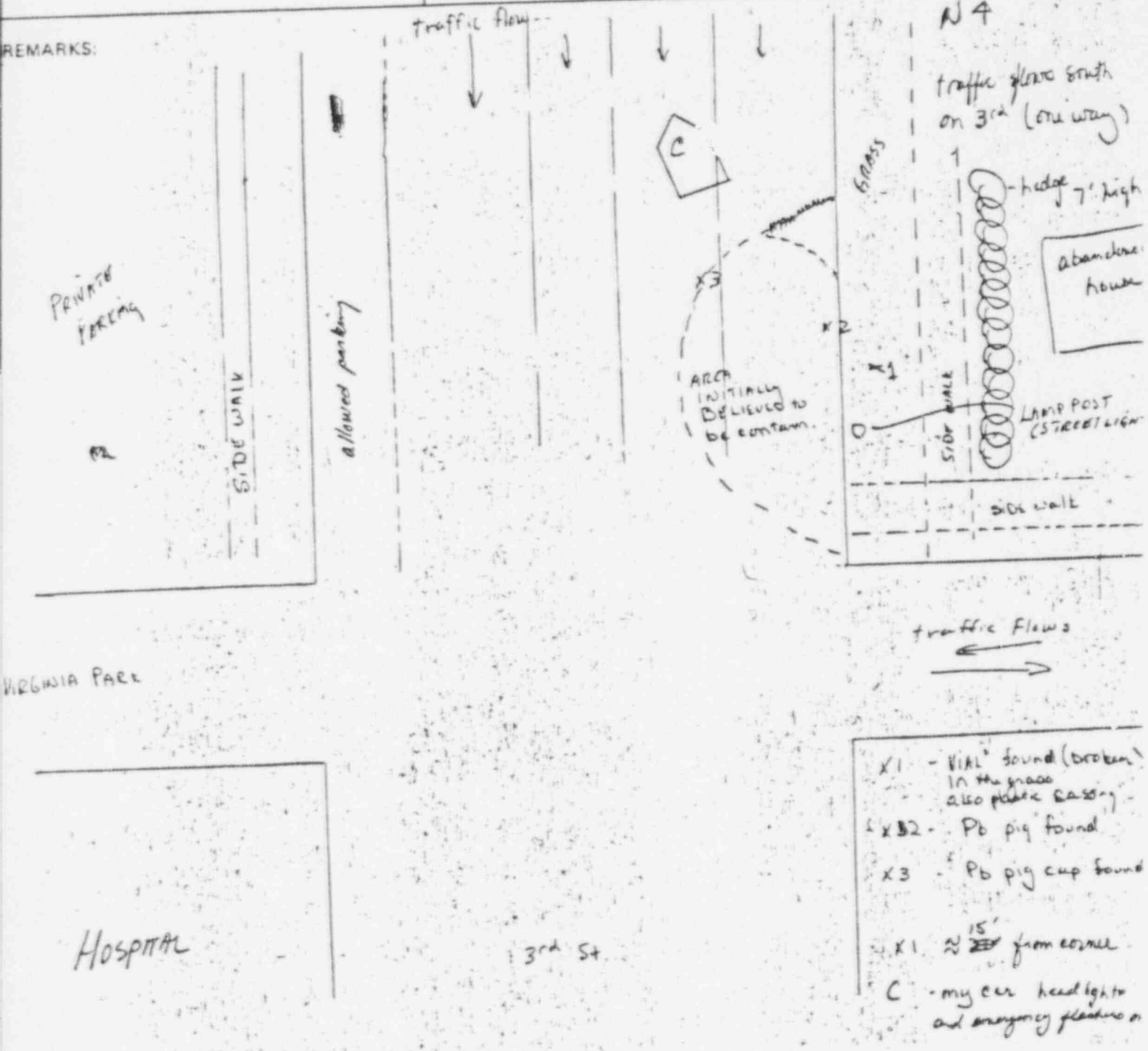
AH-800

	Expiration Date	Staff No. 66	Asst. Staff No.	Date 7/29/80
Estab. No.	Facility No.	County No. 63	County Oakland	
Estab.		Fac.		

Michigan Department of Public Health
Division of Radiological Health
3500 N. Logan Street
Lansing, Michigan 48914
Telephone: (517) 373-1410

Contacts:

REMARKS:



X1 - VIAL found (broken) in the grass also plastic casing

X2 - Pb pig found

X3 - Pb pig cup found

X1 ≈ 15' from corner

C - my car headlights and emergency flashers

STATUS	ORIGIN	CONTACT	STATUS CHANGE	MACHINE STATUS	MACHINE STATUS CHANGE	TUBE STATUS
0. Not applicable 1. Compliance 2. Pend. Disposal 3. Pend. Correctn. 4. Cease and desist	0. Not applicable 1. New 2. Renewal 3. Amendment 4. Follow-up 5. Request 6. Compla	0. Not applicable 1. Full inspection 2. Part. inspection 3. Telephone 4. Office 5. Plan Review 6. Hearing	0. No change 1. New compliance 2. Out of compliance	Compliance Non-compliance Total	Add Subtract	Compliance Non-compl. Total Tubes Inspected