U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-31890/92002(DRSS)

Docket No. 030-31890

License No. 48-26240-01 Category G1 Priority 1

Licensee: MPI Pharmacy Services, Inc.
823 North 12th Street
Milwaukee, WI 53200

Inspection Conducted: June 17, 24 and July 14, 1992

Inspectors: T. L. Simmons 10/5/92
T. L. Simmons Date
Radiation Specialist

J. T. Simmons for 10/5/92
John Jones Date
Licensing Reviewer

Approved By: B. J. Holt 10/5/92
B. J. Holt, Chief Date
Nuclear Materials Inspection
Section 1

Inspection Summary

Inspection on June 17, 24 and July 14, 1992 (Report No. 030-31890/92002(DRSS))
Areas Inspected: This special inspection was conducted to review the circumstances surrounding reported contamination of the licensee's facilities. The inspection included interviews with personnel, independent measurements, and review of survey procedures, personnel training and decontamination efforts.
Results: Of the areas inspected, two apparent violations were identified: (1) Use of unauthorized equipment to compound iodine-131 capsules and (2) Failure to perform surveys of the fume hood after compounding iodine-131. Two areas of concern were also identified: (1) Failure to immediately implement the decontamination plan and (2) Failure to perform adequate surveys.

A Confirmatory Action Letter (CAL) was issued June 22, 1992 confirming that the licensee would (a) cease compounding capsules until contamination levels inside the fume hood reached no more than 2200 dpm per 100 centimeters squared; (b) discontinue use of the unauthorized dispensing system until the license is amended; and (c) instruct personnel in the procedures described in licensee letter dated November 8, 1988 prior to compounding iodine-131.

As of August 19, 1992, the following actions have been taken to resolve the CAL issues: (a) the iodine fume hood has been decontaminated/decayed to below 2200 dpm/cm2; (b) the nitrogen gas dispensing system has been dismantled with

no further use intended; and (c) all authorized users have received instructions on the approved compounding procedures.

DETAILS

1. Persons Contacted

Janet Reuther, Manager-Pharmacy Regulatory Affairs
Robert Freissen, Facility Radiation Safety Officer
Brian Schultz, Radiopharmacist
Mark Sharafinski, Radiopharmacist
David Sielaff, Technician/Driver
Nancy Shaw, Driver
Colleen Ehnert, Secretary

2. Purpose of Inspection

This special inspection was conducted to review the circumstances surrounding reported extensive contamination of the licensee's facility. On June 17, 1992, NRC Region III received a telephone call from an anonymous individual stating that MPI Pharmacy Services, Inc. of Milwaukee, Wisconsin was seriously contaminated with iodine-131. Region III dispatched two individuals to the site to determine the extent of the contamination, confirm that the contaminant was iodine-131 and review the licensee's decontamination efforts.

3. Licensed Program and Inspection History

NRC Byproduct Material License No. 48-26240-01 was issued to MPI Pharmacy, Inc. (MPI) on September 24, 1990. The license permits production, distribution and redistribution of certain radiopharmaceuticals and sealed sources to authorized recipients. Production includes compounding iodine-131 capsules and liquid from bulk quantities.

MPI currently employs eleven individuals, three of whom are listed as authorized users in License Condition No. 11.

An initial inspection of the licensee's activities was conducted on November 22, 1991. No violations of NRC requirements were identified. A special inspection was conducted March 19-23, 1992, in response to a reported event involving MPI's delivery of a package with excessively high radiation levels to a customer. Two violations were identified: (1) Failure to adequately shield licensed material and (2) Failure to perform an adequate package survey.

4. Incident Summary

MPI compounds iodine-131 capsules at the request of its customers. Capsules are normally compounded by second shift pharmacists in a designated fume hood located at one end of the pharmacy. On Friday, June 12, 1992, two second shift authorized users were on duty. Each authorized user compounded an iodine-131 therapy capsule. Direct radiation surveys of the fume hood's exterior surface performed by

licensee personnel before the last capsule was compounded indicated that the radiation levels were within the normal levels of 4 to 5 mR/hr. No capsules were compounded on June 13th or 14th and survey records showed no change in radiation levels at the iodine fume hood. On June 15th, the 1st shift pharmacist told the 2nd shift pharmacist that the hood was "hot" meaning that the radiation levels at the fume hood face were much higher than previously noted. According to licensee representatives, radiation levels at the fume hood that morning were around 20 mR/hr. Direct radiation surveys performed later in the day showed radiation levels at the fume hood to be 11 mR/hr and wipe tests to be 290 disintegrations per minute (dpm). Notes on the survey record indicate that an unsuccessful attempt was made to reduce the radiation levels.

On the afternoon of the 15th, the 2nd shift pharmacist compounded four iodine-131 capsules in the fume hood. On Tuesday, June 16th, the 2nd shift pharmacist and the pharmacy technician removed the contents of the fume hood in an attempt to decontaminate. It is believed that during this process low level contamination was spread to the offices located outside of the restricted area. Surveys were made of both the restricted area and the unrestricted area. Decontamination efforts resulted in limited success; therefore, in accordance with their procedures, the six or eight small spots of low level contamination found in the carpet of the unrestricted area were covered. The pharmacist notified the Eastern Region Manager, James Pancy and the Corporate Compliance Officer/Corporate Radiation Safety Officer, Janet Reuther of the problem. Ms. Reuther arrived at the Milwaukee facility the next day.

On June 17th, an individual telephoned the NRC Region III office to express concerns regarding "wide spread" iodine-131 contamination. NRC staff contacted the pharmacy and was informed that there was some abnormal contamination at the facility. Two NRC staff members were dispatched to the site to confirm that the contaminant was iodine-131, to observe the licensee's decontamination efforts and to review the circumstances which may have caused the contamination.

5. Inspection Findings

Using a Nuclear Data portable multi-channel analyzer with a sodium iodide detector, the inspectors confirmed that the contamination was iodine 131.

The inspectors observed approximately eight small regions on the carpet in the unrestricted office area where the licensee had found contamination. The maximum contamination levels detected by the inspectors using a pancake probe with an efficiency of 60% for iodine-131, were approximately 4200 dpm at the surface of the carpet. This compared favorably with the results obtained from the licensee. The licensee attempted to remove all contamination; however, areas that could not be completely decontaminated were covered, identified to the staff and allowed to decay. The inspectors conducted direct radiation surveys of the office area, the bathroom, the pharmacy entrance and the

lunch room. No radiation levels in excess of 10 CFR Part 20 limits for unrestricted areas were found. At the request of the inspectors, the pharmacy technician conducted random gross smears of the lunch room, a computer area, desk, bathroom door, and the laboratory floor. The smears were assayed onsite and the results were less than the licensee's action level for unrestricted areas (220 dpm). A review of licensee surveys showed no contamination in delivery vehicles or at the loading dock.

The inspectors observed Ms. Reuther and others as they smeared the entire pharmacy floor. Contamination was found on the floor in front of the iodine fume hood. The area was decontaminated to less than 2200 dpm per 100 square centimeters.

During interviews with the pharmacists, the inspectors learned that a nitrogen gas dispensing system had been used to compound capsules. License Condition No. 27 requires the licensee to conduct its program in accordance with the statements, representations, and procedures contained in certain referenced documents. Referenced letter dated November 8, 1988 describes the equipment and procedures to be employed when making iodine-131 capsules. The NRC approved procedure indicates that a micropipette would be used to dispense iodine into prepared capsules. However, for at least two years the nitrogen gas dispensing system, which dispenses iodine under pressure into the prepared capsules, has been used. The device was designed by a former pharmacist to precisely dispense a specific quantity of iodine into each capsule. The designer of the device left the facility and is no longer able to monitor its accuracy and provide maintenance. Use of the unapproved nitrogen gas dispensing system to compound iodine capsules is a violation of License Condition No. 27. There was no indication that the dispensing system was a contributing factor to the contamination. The pharmacists denied that the system was improperly used or that it failed to function as designed.

Thyroid bioassays were performed on all individuals who entered the pharmacy between June 11th and June 17th. The inspectors reviewed the results which were below 40 MPC hours. External dosimetry reports for the month of June were reviewed by the inspectors. Both whole body and extremity exposures were well below 10 CFR Part 20 limits. In addition, air sampling performed for the same period indicated a 50% rise in the iodine effluent; however, the releases were still within 10 CFR Part 20 Appendix B limits. On Tuesday, minor contamination was found on the shoes of two individuals. The shoes were successfully decontaminated. No other personnel were contaminated. Contamination was confined to the licensee's facility.

As previously stated, License Condition No. 27 requires the licensee to conduct its activities in accordance with certain referenced documents. Item 14 of a referenced letter dated November 8, 1988, requires the licensee to survey the fume hood area after compounding and to promptly dispose of contaminated materials. The root cause of this event appears to be that during the compounding of capsules on Friday afternoon on June 12th, the fume hood became grossly contaminated. Surveys were not

performed after preparing the capsules, therefore, contaminated articles were not disposed of as required. Failure to perform surveys of the fume hood area following compounding iodine-131 capsules is a violation of License Condition No. 27.

On Monday morning when both pharmacists realized that the fume hood was grossly contaminated they should have immediately reviewed and implemented their decontamination procedures to preclude the spread of iodine into the unrestricted area. The inspectors expressed concern that licensee personnel failed to recognize the potential safety hazard by not promptly implementing the decontamination procedure.

The inspectors questioned the pharmacist on the surveys that were conducted on June 13th and 14th. The survey records indicated no unusual radiation levels at the fume hood. The pharmacist maintained that the surveys had been performed. The inspectors concluded that if the surveys had been adequately conducted the pharmacist would have detected the abnormal radiation levels and the resulting contamination could have been confined to the laboratory.

A Confirmatory Action Letter (CAL) was issued to the licensee on June 22, 1992 based on an understanding between Ms. Reuther and NRC Region III staff that the following actions would be taken:

1. The iodine fume hood would not be used until smear tests results were no more than 2200 dpm/100 cm2.

2. The nitrogen gas dispensing system would not be used until the licensee received an amendment to its license authorizing the use of this device.

3. Prior to compounding capsules or liquid iodine-131, all authorized users would be instructed on the procedures described in licensee letter dated November 8, 1992.

In response to the CAL, the Radiation Safety Officer confirmed that as of August 1992:

1. The iodine fume hood had been decontaminated to below 2200 dpm/100 cm2.

2. The nitrogen gas dispensing system had been dismantled with no further use intended.

3. All authorized users have been instructed on the procedures described in licensee letter dated November 8, 1992.

Two violations of NRC requirements were identified. Two areas of concern were addressed.

6. Exit Meeting

The event and its causes, the apparent violations and corrective actions were discussed with Mr. R. Freissen on June 24, 1992 and with Ms. Reuther on July 7, 1992. In a letter dated July 10, 1992, the licensee discussed its findings and subsequent corrective actions.

The licensee did not identify any information contained in this report as proprietary.