U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-18558/89001(DRSS)

Docket No. 030-18558 License No. 21-24380-01

Licensee: Michael Lala, M.D.
23800 Orchard Lake Road
Farmington Hills, MI 48024

Inspection At: Garden City Medical Center; Wayne Westland Clinic and Alpar Associates

Inspection Conducted: August 23-25, 1989

Inspector: J. W. Patterson
Radiation Specialist
Date 10/20/89

Reviewed By: R. J. Caniano, Chief
Nuclear Materials Safety Section 2
Date 10/20/89

Approved By: Bruce S. Mallett, Ph.D., Chief
Nuclear Materials Safety Branch
Date 10/23/89

Inspection Summary

Inspection on August 23-25, 1989 (Report No. 030-18558/89001(DRSS))
Areas Inspected: This was an unannounced special inspection conducted at three of the licensee's facilities in the Detroit metropolitan area in response to receipt of five allegations concerning the licensee's Nuclear Medicine operations. The inspection included a review of licensee records and procedures, and interviews of licensee representatives.
Results: Two of the five allegations were substantiated and five apparent violations of NRC requirements were identified. (1) failure to survey incoming packages, License Condition 15. (2) failure to maintain receipt and transfer records 10 CFR Part 30.51(a). (3) failure to record the results of dose calibration records, License Condition 15. (4) failure to conduct leak test of sealed references sources, License Condition 17. (5) failure to maintain records of surveys performed prior to disposal of waste, 10 CFR Part 20.401(b).

## DETAILS

1. Persons Contacted

*Michael Lala, M.D.
Lara Hawes, R.T.
Yvonne Griffin, Nuclear Medicine Technologist
Kenneth W. DeByle, D.O.
Michael Slugat-Technician

*Attended exit interview on August 25, 1989.

2. Licensed Program and Inspection History

Michael Lala, M.D. is authorized for Groups I-III, iodine-125 for bone mineral analysis and iodine-131 for hyperthyroidism. The current license authorizes the aforementioned materials at 32 locations throughout the metropolitan Detroit area. Michael Lala, M.D. is the Radiation Safety Officer and one of the three authorized users named in License Condition No. 12. Licensed material is currently obtained from Syncor, Inc.

The last routine inspection of this license was on April 11, 1985, at which time 2 violations were identified. The violations were as follows:

a. Failure to perform dose calibrator linearity tests at the required frequency, and

b. Failure to use a method of leak testing sealed sources capable of detecting .005 microcuries and failing to maintain records of leak tests.

3. Purpose of Inspection

This was conducted in part to review allegations received by the NRC Region III office on April 28, 1989, concerning certain practices at Dr. Lala's Garden City, Wayne Westland, and South Allen Radiology facilities. The inspection also included a routine inspection of Dr. Lala's radiation safety program as authorized by his NRC license. The inspection included a review of records, personnel interviews, and observations. The authorized facilities of Garden City, Wayne Westland, and Alpar Associates were visited during the course of this inspection. The South Allen facility was not visited due to recent closure of that facility (although records were reviewed) and the visit to Alpar Associates was limited to surveys due to its recent closure. Close out surveys for South Allen and Alpar have been submitted to the NRC Region III office. Records for South Allen and Alpar Associates are being stored at the Garden City facility where they were reviewed by the inspector.

4. Specific Allegations

The specific allegations received by the NRC Region III office on April 28, 1989, are as follows:

a. Possible record falsification by a new employee pertaining to the South Allen facility for the time period beginning in April 1989.

b. Incoming packages containing radiopharmaceuticals were not surveyed on March 31, April 3, and April 6, 1989 upon their receipt at the Wayne Westland facility.

c. Receipt and transfer records were not maintained at the Garden City facility for April 13 and 14, 1989.

d. Dose calibrator constancy checks were not performed at the Wayne Westland facility on March 31, April 3 and April 6, 1989.

e. Radiopharmaceuticals were not assayed in the dose calibrator prior to patient injections at the Wayne Westland facility on March 31, April 3 and April 6, 1989.

5. NRC Followup of Allegations

Allegation No. 1. Possible record falsification by a newly hired technician.

Around April 7, 1989, Dr. Lala's Chief Technologist resigned from Dr. Lala's employment. According to the alleger and a report to the NRC on April 21, 1989, the individual prior to his resignation had removed numerous documents pertaining to quality control from the South Allen facility. At the request of Dr. Lala, the individual returned the records on April 21, 1989, in disarray. The purpose for removing the documents supposedly was to reorganize them.

According to the alleger, it was believed that a recently hired technician (hired around April 14, 1989) may have been fabricating records in order to reorganize those records found to be in disarray when they were returned on April 21, 1989.

From discussions with licensee representatives and the individual who allegedly falsified records, the inspector determined that the individual had not been employed by Dr. Lala during the time frame in question. (The individual had been employed by Dr. Lala during the 1984 time frame.) The individual in question when interviewed did indicate that in April 1989, as a favor to Dr. Lala, he did attempt to reorganize the records that had been returned in disarray on April 21, 1989. The individual denied that at any time did he ever fabricate or alter any of those records.

During the course of this inspection, the inspector reviewed numerous records pertaining to Wayne Westland, Alpar Associates, South Allen, and Garden City. These records included survey records, leak test records, receipt and transfer records, waste disposal records, instrument calibration

records, and personnel monitoring records. There was no indication of any record fabrications. In addition, none of the individuals identified in Section 1 of this report including Dr. Lala had any knowledge of any record fabrication for any of Dr. Lala's facilities.

This allegation was not substantiated.

No violations of NRC requirements were identified.

Allegation No. 2. Incoming packages containing radiopharmaceuticals were not surveyed on March 31, April 3, and April 6, 1989 upon their receipt at the Wayne Westland facility.

The licensee's application dated August 29, 1984, referenced in License Condition No. 15 describes the licensee's procedures for the surveying of incoming packages containing radiopharmaceuticals. This consists of performing radiation measurements at the surface and at three feet from the package and taking wipe tests of the final source container. Records are to be maintained of the above mentioned surveys and wipes.

A review of records of incoming packages at the Wayne Westland facility revealed that on March 31 and April 6, 1989, all required radiation surveys and wipe tests were performed upon receipt of the licensee's incoming packages containing radiopharmaceuticals. For April 3, 1989, it was determined by way of interviews and record reviews including patient logs and schedules that no patient studies were performed and that no packages were received at Wayne Westland.

Further review however of the licensee's records of incoming packages revealed that for the period January 5, 1988, until January 24, 1989, no radiation surveys or wipe tests were conducted on any incoming packages received at the Wayne Westland facility. According to the technologist employed at Wayne Westland, the required surveys and wipe tests commenced on January 24, 1989, and have continued to date. This was confirmed by record review. The licensee's failure to conduct required radiation surveys and wipe tests of incoming packages containing radiopharmaceuticals at the Wayne Westland facility from January 5, 1988 until January 24, 1989 constitutes a violation of License Condition No. 15.

A review of records of incoming packages for Garden City, Alpar Associates and South Allen revealed that radiation surveys and wipe tests had been conducted as required for all incoming packages of radiopharmaceuticals.

Although the allegation was not substantiated for the specific dates given in the allegation, it was substantiated for the time period January 5, 1988, until January 24, 1989. One apparent violation of NRC requirements was identified.

Allegation No. 3. Receipt and transfer records were not maintained at the Garden City facility for April 13, and 14, 1989.

10 CFR Part 30.51(a) requires licensees to keep records showing the receipt, transfer and disposal of byproduct material.

Receipt and transfer records pertaining to Garden City were reviewed by the inspector. That review revealed that from May 1987 through July 3, 1989, the licensee did not keep any records pertaining to the receipt and transfer of any licensed material. Subsequent to July 3, 1989, records were maintained.

With regards to the Wayne Westland facility it was determined that no records of receipt and transfer of licensed material were maintained from September 25, 1988, through April, 1989. Subsequent to April 1989 records were maintained.

The failure of the licensee to maintain records of receipt and transfer records from May 1987 through July 3, 1989, at Garden City and from September 25, 1988, through April 1989, at Wayne Westland constitutes a violation of 10 CFR Part 30.51(a).

No discrepancies were identified with regards to receipt and transfer records pertaining to Alpar Associates and South Allen.

The allegation was substantiated and one apparent violation of NRC requirements was identified.

Allegation No. 4 Dose calibration constancy checks were not performed at the Wayne Westland facility on March 31, April 3, and April 6, 1989.

The licensee's application dated August 29, 1984 as referenced in License Condition No. 15 describes the licensee's procedures for conducting dose calibrator calibrations. This includes the requirements for constancy on day of use, quarterly linearity, annual accuracy and geometrical variation at installation. Records are to be maintained of the aforementioned tests.

A review of records and interviews with personnel for the Wayne Westland facility determined that for the dates March 31 and April 6, 1989, the daily constancy tests were performed as required. As previously stated in Allegation No. 2, no patient studies were performed on April 3, 1989, thus the dose calibrator was not used. All other dose calibrator tests were performed as required.

With regards to Garden City, it was determined from personnel interviews that although constancy tests were performed as required the licensee failed to record the results of the tests for the period May 15, 1987, through September 1, 1988. The licensee's failure to record the results of the constancy tests constitutes a violation of License Condition No. 15. All other dose calibrator tests were performed as required.

With regards to Alpar Associates and South Allen all required dose calibrator tests had been conducted as required.

Although the allegation was not substantiated, one apparent violation of NRC requirements was identified.

Allegation No. 5. Radiopharmaceuticals were not assayed in the dose calibrator prior to patient administrations at the Wayne Westland facility on March 31, April 3, and April 6, 1989.

The licensee's application dated August 29, 1984, as referenced in License Condition No. 15 states that each patient dose will be assayed in the dose calibrator prior to administration.

With regards to the Wayne Westland facility a review of records and discussions with licensee personnel determined that on March 31 and April 6, 1989, all patient doses administered were assayed in the dose calibrator and recorded as required. As previously indicated no patient studies were conducted on April 3, 1989.

With regards to Garden City, Alpar Associates, and South Allen, no discrepancies were noted with regards to assaying of patient doses. Record reviews and interviews with personnel revealed that all patient doses had been assayed as required prior to patient administrations.

The allegation was not substantiated and no violations of NRC requirements were identified.

6. Other Areas Inspected

In addition to the review of allegations, the inspector also reviewed the following aspects of the licensee's program.

a. Leak Tests

License Condition No. 17(a)(1) requires the licensee to perform leak teste of their sealed sources at 6 month intervals. At each of the three facilities visited during this inspection, the licensee was in possession of or had been in possession of a cesium-137 reference source (approximately 100 microcuries) and a cobalt-57 reference source (approximately 2 millicuries).

With regards to the Wayne Westland facility the licensee failed to conduct leak tests of their cesium-137 calibration source at the required frequencies. Specifically, a leak test conducted on January 12, 1987, was not repeated again until August 20, 1987, a period exceeding six months. Subsequent to August 20, 1987, leak tests had been conducted as required. The licensee's failure to conduct leak tests at the required interval in 1987 constitutes a violation of License Condition No. 17(a)(1).

No discrepancies were identified for Garden City, Alpar Associates, and South Allen regarding leak tests.

One apparent violation of NRC requirements was identified.

c. Personnel Monitoring

The licensee's application dated August 29, 1984, as referenced in License Condition No. 15 states that whole body and extremity monitoring devices will be worn and exchanged on a monthly basis. The licensee currently uses the services of Siemens Co. for this service. A review of film badge results for those facilities visited revealed an average of 20 millirem exposure (whole body and extremity) per month for the period January 1987 to June 9, 1989.

No violations were identified.

d. Radiological Protection Procedures

The licensee's radiation protection program is described in their application dated August 19, 1984, as referenced in License Condition No. 15. Except noted elsewhere in this report the licensee appears to be following those procedures. The licensee was observed to be wearing the required monitoring devices, laboratory coats and utilizing syringe shields. There was no evidence of smoking, eating or storing of food in any restricted area.

No violations were identified.

e. Postings, Labeling

All areas inspected during this inspection were found to posted with required signs and notifications. Packages and radiopharmaceuticals were all found to be labelled as required.

No violations were identified.

f. Waste Disposal

The licensee's waste disposal program is described in their application dated August 24, 1989, as referenced in License Condition No. 15 and basically consists of holding materials for decay until radiation surveys have reached background levels. 10 CFR Part 20.401(b) requires the licensee to maintain records of radiation surveys conducted.

From interviews with licensee representatives and record reviews, the inspector was informed that for the most part all radioactive materials are returned to Syncor for disposal. On occasion the licensee disposes of residual radioactive materials (technetium-99m) by holding it for decay. According to the licensee, from approximately September 1984 until June 5, 1989, records of radiation surveys of waste disposed of by holding it for decay were not maintained for the Wayne Westland facility. According to the licensee, the material was held for decay and was surveyed to ensure that it was at background prior to its disposal as normal trash. As

previously stated, the material was residual technetium-99m products. The licensee's failure to maintain records of radiation surveys constitutes an apparent violation of 10 CFR Part 20.401(b).

No problems were identified with regards to waste disposal at the Alpar Associates, Garden City, and South Allen.

One apparent violation of NRC requirements was identified.

g. Storage of Materials

Storage of materials at the Wayne Westland and Garden City facilities was found to be as required by 10 CFR Parts 20.207(a) and (b). No material was present at Alpar Associates and as previously mentioned, South Allen was not visited.

No violations of NRC requirements were identified.

h. Independent Measurements

Radiation surveys were conducted at each of the visited facilities using a Xetex 305B survey instrument. With regards to the Garden City and Wayne Westland facilities no area surveyed was found to be in excess of 0.4 milliroentgen per hour. With regards to Alpar Associates no radioactive material was present and no detectable radiation levels were observed. As previously stated, Alpar Associates recently stopped performing nuclear medicine procedures and has submitted a closeout survey to the NRC Region III office.

No violations of NRC requirements were identified.

i. Reports and Notifications

The licensee was found to be in compliance with the reporting requirements of 10 CFR Parts 20.402, 20.403, and 20.405 and 10 CFR Part 35.33. No incidents or reportable misadministrations had occurred at any of Dr. Lala's facilities since the last inspection.

No violations of NRC requirements were identified.

7. Exit Interview

At the conclusion of this inspection, the NRC representative informed Dr. Lala of the apparent violations and allegations. No written material was left with the licensee. In addition, no proprietary information is included in this inspection report.