U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-02435/89-001

Docket No. 030-02435

License No. 29-01423-01 Priority 3 Category G

Licensee: United Hospitals of Newark

15 South Ninth Street
Newark, New Jersey 07107

Facility Name: Presbyterian Hospital Unit

Enforcement Conference At: King of Prussia, Pennsylvania

Enforcement Conference Conducted: November 14, 1989

Prepared by: Teresa Hall Darden 12/12/89
Teresa Hall Darden, Health Physicist date

Approved by: M. S. Shanbaky 12/12/89
Mohamed M. Shanbaky, Chief date
Nuclear Materials Safety Section A

Conference Summary: Enforcement Conference held at the Region I office in King of Prussia on November 14, 1989, to discuss the violations identified in Inspection No. 030-02435/88-001, relative to management oversight of the licensed program, falsified records of required daily dose calibrator constancy tests, the circumstances that led to the falsification and the licensee's corrective actions. Enforcement options available to the Commission were reviewed.

DETAILS

1.0 Attendees

United Hospitals of Newark

Francis Blackman, M.D., Vice President of Medical Affairs
A. Brenner, M.D., Nuclear Medicine Physician

NRC

Malcolm R. Knapp, Director, Division of Radiation Safety and Safeguards
Lee H. Bettenhausen, Chief, Nuclear Materials Safety Branch
Daniel J. Holody, Enforcement Officer
Mohamed M. Shanbaky, Chief, Nuclear Materials Safety Section A
Teresa Hall Darden, Health Physicist

2.0 Summary

On November 14, 1989, representatives of the United Hospitals of Newark met with NRC Region I representatives in the Region I office at King of Prussia, Pennsylvania. In an opening statement, an NRC representative explained the purpose of the Enforcement Conference.

Licensee representatives acknowledged the violations that were identified during NRC Inspection No. 88-001 and discussed the organizational and staffing changes that have taken place since the inspection. Dr. Brenner stated that he was unaware that the Nuclear Medicine Technologist (NMT) had acknowledged to the NRC Office of Investigations (OI) Investigator that she had, in fact, falsified the dose calibrator daily constancy records, until he read the synopsis of the OI report shortly before the conference. He discussed the conditions involving staff shortages in the Nuclear Medicine Department and the circumstances that possibly led to the NMT to perceive the need to falsify daily constancy test records. He then described the following corrective actions that have been implemented since the NRC inspection:

- As of September, 1988 the Nuclear Medicine staff of two was increased to a full staff of five technologists.

- In addition to the present long term consultant's visits, another consultant also visits the department, reviews the program, performs observations and audits of the department during daytime working hours at least once in each month.

- Audit Reports presently are discussed with the Nuclear Medicine Physician and signed by the same Physician.

- The hospital recently initiated a Quality Improvement Program with a committee composed of representatives from all departments within the hospital. Included in their site overview are twice yearly audits of such radiation program specifics as dose calibrator tests and records.

- A Quality Assurance Program has been implemented in the Nuclear Medicine Department with one individual responsible for surveys, daily tests, waste monitoring and waste disposal.

- A built in management control system is in place to ensure the quality and integrity of reported data. The system requires that test results be reviewed by someone other than the person who performed the test.

- Radiation Safety Committee Meetings are now scheduled through the Department of Medical Affairs. This assists management in identifying problems as well as ensuring adequate representation from all designated departments.

- Since the NMT suggested that an electrical power surge could be responsible for changes in dose calibrator response, management now requires that power voltage be checked daily and that records be maintained.

Dr. Brenner stressed that, from his review of available information, no patient received an incorrect dose of a radiopharmaceutical.

Dr. Blackman stated that the present administration is committed to maintaining the program in accordance with regulatory requirements.

NRC representatives explained enforcement procedures and options available to the Commission.