# U.S. NUCLEAR REGULATORY COMMISSION REGION I

Report Nos. 030-01325/94-002 030-30758/94-002

Docket Nos. 030-01325

030-30758

License Nos. 08-03604-03

08-28270-01

Licensee:

Washington Hospital Center

Medlantic Research Foundation

110 Irving Street, N.W. Washington, D.C. 20010

108 Irving Street, N.W. Washington, D.C. 20010

Facility Name:

Washington Hospital Center

Medlantic Research Foundation

Inspection At:

Washington, D.C.

Washington, D.C.

Inspection Conducted:

January 10-11, 1994

January 10-11, 1994

Prepared by: 9772

David G. Mann, Health Physicist

James P. Dwyer, Sr. Health Physicist

Approved by:

Jenny M. Johansen, Chief

Medical Inspection Section

Conference Summary: An enforcement conference was held at the NRC Region I Office in King of Prussia, Pennsylvania on February 10, 1994, to discuss the circumstances surrounding the apparent whole body exposures in excess of two regulatory limits that occurred during the third and fourth quarters of 1993. The licensee's investigation of the incident, the licensee's actions to prevent similar recurrences, and the findings of the special inspection conducted on January 10-11, 1994 were reviewed.

#### DETAILS

## 1. Attendees

### Medlantic Research Foundation

Barbara V. Howard, Ph.D., President & Radiation Safety Officer James C. Knight, Vice President Operation & Finance

### Washington Hospital Center

Mark H. Merrill, M.S.P.H., Vice President Operations & Administrative Services Gerald S. Johnston, M.D., Radiation Safety Committee Chairman Kenneth D. Williams, M.S., Radiation Safety Officer John L. Zurita, M.S., R.T.N., Manager, Nuclear Medicine Department

#### NRC

Charles W. Hehl, Director, Division of Radiation Safety and Safeguards Ronald R. Bellamy, Ph.D., Chief, Nuclear Materials Safety Branch Jenny M. Johansen, Chief, Medical Inspecting Section Daniel J. Holody, Enforcement Officer James P. Dwyer, Senior Health Physicist Theresa H. Darden, Senior Health Physicist David G. Mann, Health Physicist

# 2. Summary

Representatives of Medlantic Research Foundation (MRF) and the Washington Hospital Center (WHC) met with NRC representatives on February 10, 1994, at the Region I Office in King of Prussia, Pennsylvania. In opening remarks, Mr. Hehl and Mr. Holody explained the purpose and scope of the conference.

Dr. Howard and Mr. Merrill described the relationship between MRF and WHC. A Board of Governors, entitled the Medlantic Health Care Group, owns three not-for-profit institutions; WHC, MRF, and the Rehabilitation Hospital. These institutions are physically located on the same campus. MRF is a separate entity which manages and oversees research conducted within the MRF facility, as well as the WHC and Rehabilitation Hospital facilities. The overexposure is attributed to the one project which involved both the WHC and MRF.

Dr. Howard and Mr. Merrill acknowledged that the inspection report was factual. Neither could provide a plausible cause for the exposure recorded on the film badges. Both discussed changes in their respective programs to prevent recurrence of the other violations identified during the special inspection. For MRF these changes included: restricting authorization to use radioactive material at MRF facilities to those individuals

employed by MRF; centralizing the radioactive materials ordering and receipt procedure; requiring that film badges issued by MRF be worn only within the MRF building; requiring employees to notify MRF radiation safety staff regarding any use of radioactive material outside the MRF facility; adhering to the conditions of their license regarding monthly film badge processing, and holding quarterly radiation safety committee meetings. The WHC program changes included: centralizing the radioactive materials ordering and receipt procedure through the nuclear medicine department to assure that license limits are not exceeded and appropriate records are kept; requiring researchers to notify the radiation safety committee prior to beginning an approved research project to assure proper radiation safety procedures are followed, such as providing proper personnel monitoring, providing appropriate supervisory oversight, and requiring appropriate radiation exposure and contamination survey's. The WHC representatives indicated that significant radiation safety staffing changes had occurred within the previous year. These changes included the radiation safety officer, the director of nuclear medicine, the radiation safety committee chairman, and the manager of nuclear medicine.

Dr. Howard stated that, at the time the event occurred, she was aware of a requirement to notify the NRC in the event of an overexposure. However, she was not aware that the required notification time was within 24 hours of discovery.

Both Dr. Howard and Mr. Merrill indicated that closer coordination between the radiation safety committees of both institutions was warranted. Dr. Howard indicated that both radiation safety committees will have to review projects requiring Institutional Review Board approval, even if one of the committees will not be involved in the project.

Mr. Merrill stated that the WHC administration, the radiation safety officer, and the radiation safety committee chairman are currently reviewing the licensed program to evaluate staffing resources. It is anticipated that this evaluation will be completed in February 1994.

Mr. Holody discussed with both licensees the enforcement options available to the NRC.

Following the conclusion of this meeting, the WHC representatives provided further information to the NRC staff regarding the control of their nuclear pacemakers. Mr. Williams discussed their proposed initiative to send registered letters to all nuclear pacemaker recipients on a quarterly basis. This may include sending letters to the patients' physician, retirement or nursing home, or next of kin.