U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-01325/97-001

Docket No. 030-01325

License No. 08-03604-03 Priority 1 Category G1 Program Code 02110

EA No. 96-385

Licensee: Washington Hospital Center
110 Irving Street, N.W.
Washington, DC 20010-2975

Facility Name: Washington Hospital Center

Predecisional Enforcement Conference Conducted at: King of Prussia, PA

Predecisional Enforcement Conference Conducted: January 31, 1997

Prepared by: Richard W. McKinley 4/8/97
Richard McKinley, Health Physicist Date

Teresa Darden 4/8/97
Teresa Darden, Senior Health Physicist Date

Approved by: Ronald R. Bellamy April 8, 1997
Mohamed M. Shanbaky, Chief Date
Nuclear Materials Safety Branch

Predecisional Enforcement Conference Summary: A transcribed predecisional enforcement conference was held at NRC Region I in King of Prussia, Pennsylvania, on January 31, 1997, to discuss the apparent violations identified as a result of NRC Inspection No. 030-01325/96-001 and NRC Office of Investigation findings that licensee staff willfully failed to perform bioassays. Enforcement options available to the Commission were discussed.

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Details

1.0 Attendees

Washington Hospital Center

Oliver Crump, Vice President, Ambulatory Services & Clinical Affairs
Billy G. Bass, DSc., Radiation Safety Officer
Gerald Johnston, M.D., Director of Nuclear Medicine
John Zurita, MSc., Manager, Nuclear Medicine
Dennis Dionne, Administrative Director of Radiology Services

NRC

Charles W. Hehl, Director, Division of Nuclear Material Safety
James P. Dwyer, Acting Chief, Nuclear Materials Safety Branch 1
Teresa Hall Darden, Senior Health Physicist
Richard McKinley, Health Physicist
Tracy Walker, Senior Enforcement Specialist
J. Bradley Fewell, Regional Attorney
*Nader Mamish, Enforcement Specialist

*By telephone

2.0 Summary

Mr. Hehl opened by stating that the purpose of the meeting was to provide the licensee an opportunity to discuss the events surrounding the apparent violations, to accept or deny the apparent violations, provide corrective actions taken as a result of the apparent violations, and provide any additional information that would enable the Commission to make an enforcement decision. The licensee was provided an opportunity to identify any inaccuracies in the inspection report.

The apparent violations were stated. The licensee acknowledged that the violations generally occurred as described in the inspection report with the exception of the requirement for authorized users to have bioassays performed after each iodine-131 therapy preparation and/or administration. The Chairman of the Radiation Safety Committee/Director of Nuclear Medicine (CRSC/DNM), who is also an authorized user, stated that "from his reading of the regulations, he did not need to have a bioassay performed after each iodine-131 therapy administration." The Radiation Safety Officer (RSO) explained that even though their standard operating procedure requires each member of the radiopharmaceutical therapy team to measure their thyroid burden from 24 to 72 hours after patient dose administration, the authorized users give instructions to the patients and then usually stand at the door or exit the patient room while the nuclear medicine technologist administers the dose of iodine-131. The CRSC/DNM stated that if the authorized user remained in the patient's

room during dose administration, then bioassays were performed. The CRSC/DNM acknowledged that there were occasions where he did not have a bioassay performed but that on these occasions, he was out of the patient's room at the time of dose administration. The CRSC/DNM stated that he may have violated standard operating procedures but he did not violate the regulations. The RSO indicated that the apparent violations were not willful but rather were inadvertent oversights. He and the Nuclear Medicine Manager then provided an overview of the corrective actions taken prior to and subsequent to the NRC inspection. These included: (1) visual reminders to perform bioassays; (2) implementation of a more restrictive disciplinary policy which incorporates written reprimands leading to suspension and/or possible termination of the employee; (3) appointment of a higher level management representative to serve on the Radiation Safety Committee; (4) acquisition of a new detector instrument with a pancake probe that is directionally sensitive; (5) survey of all individuals involved in brachytherapy procedures prior to their leaving the operating room; (6) installation of a portal monitor that monitors all waste leaving the facility; (7) training has been completed for all individuals required to perform bioassays; and (8) plans have been initiated to have an audit performed of the radiation safety program by a consultant. The licensee reiterated their commitment to comply with all regulatory requirements and license conditions.

The Senior Enforcement Specialist explained the enforcement options available to the Commission.

The meeting was adjourned.