U.S. NUCLEAR REGULATORY COMMISSION
REGION I

Report No. 030-00116/92-003

Docket No. 030-00118

License No. 06-09522-02 Priority 1 Category G3

Licensee: Greenwich Hospital Association
1 Perryridge Road
Greenwich, Connecticut 06830

Facility Name: Greenwich Hospital Association

Enforcement Conference Conducted At: King of Prussia, Pennsylvania

Enforcement Conference Conducted On: December 8, 1992

Prepared By: _____ 12-28-92
Sattar Lodhi, Ph.D., Health Physicist Date

Approved By: _____ 12-31-92
for Mohamed Shanbaky, Ph.D., Chief Date
Medical Inspection Section

Conference Summary: An Enforcement Conference was held at NRC Region I Office in King of Prussia, Pennsylvania on December 8, 1992 to discuss the reported therapeutic misadministration and the violations identified during the special inspection conducted on November 16, 1992. The corrective actions taken and planned by the licensee since the inspection were also discussed. Enforcement options available to the Commission were explained.

DETAILS

1.0 Attendees

Greenwich Hospital Association:

L. Giddings, Vice President, Ambulatory Care
M. Towers, Risk Manager
D. Fass, M.D., Authorized User
R. Sgambato, Director of Radiology & Radiation Safety Officer
D. Agrawal, Radiation Physicist
E. Pritchard, Quality Executive
A. Schultz, General Counsel

NRC:

S. Shankman, Deputy Director, Division of Radiation Safety and Safeguards
J. Johansen, Acting Chief, Nuclear Materials Safety Branch, DRSS
D. Holody, Enforcement Officer, RI
K. Smith, Regional Counsel, RI
T. Darden, Acting Chief, Medical Inspection Section
S. Lodhi, Health Physicist
P. Santiago, NRC HQ/Office of Enforcement
J. Smith, NMSS/HQ

2.0 Summary

Representatives of Greenwich Hospital Association met with NRC representatives on December 8, 1992 in the Region I Office at King of Prussia, Pennsylvania. In her opening remarks, Dr. Susan F. Shankman explained the purpose of the conference. The Enforcement Officer explained to the licensee the NRC's Enforcement Policy.

Dr. Shankman asked the licensee if there were any omissions of facts or corrections that they noted in the NRC Inspection Report sent to them on November 27, 1992. The licensee had a written response to the report and submitted a copy of the letter dated December 8, 1992 addressed to Richard Cooper (enclosure 1). The licensee's General Counsel stated that they viewed this incident with utmost seriousness and emphasized their continued commitment to provide quality care and strict adherence to all regulatory requirements related to the conduct of their licensed activities. The licensee then elaborated on the immediate actions taken to prevent similar incidents. These actions included: immediate replacement of the teletherapy physicist; disciplinary actions against the two radiation therapy technologists involved in the exposure time calculation; institution of a more comprehensive disciplinary policy; a new requirement that two individuals perform mathematical calculations independently

and that the calculations be verified by the teletherapy physicist; inclusion of a sign off sheet in the patient's chart to be signed by individuals performing mathematical calculations and by the teletherapy physicist prior to administration of treatment; and a new mandatory training program for all personnel involved in radiation therapy (enclosure 2). The licensee also stated that an independent audit of the program will be performed in six months to assess the effectiveness of these actions followed by an additional audit six months later. The authorized user (Oncologist) described the sequence of events that led to the misadministration. He stated that the review of patient's chart by the teletherapy physicist was inadequate in that he did not notice the changes in the chart or perform the required calculations to verify the treatment dose. He also stated that the patient's referring physician is following his progress and has not reported any adverse effects as a result of this misadministration (enclosure 2). He also stated that Bendheim Cancer Center is a part of Greenwich Hospital and not a separate institution as was stated in the inspection report.

With reference to the misadministration caused by the miscalculation, the Licensee stated that no evidence of a similar error was found in a review of approximately 100 randomly selected charts of the patients who were treated at the facility in the past two years (1991-92). The review was conducted by the new teletherapy physicist (enclosure 2). The licensee also stated that this number represented about 25% of the total number of patients treated at the facility during the past two years.
Also, the licensee stated that although the review was inadequate the procedure in the Quality Management Program was followed in that the health physicist did review the chart and calculations as indicated by his initials on the records and therefore the licensee was not in violation of 10 CFR 35.25(a) but a human error occurred. The licensee acknowledged that a violation of 10 CFR 35.32(a)(1) occurred when the authorized user did not sign and date the written directive. Mrs. Darden said that violations by those in the employ of the licensee are the responsibility of the licensee.

The licensee also submitted requests to amend their licenses to change the respective Radiation Safety Officer. Additionally, the licensee stated the State of Connecticut would not approve their request to hire a full time teletherapy physicist. Dr. Shankman requested that they submit the necessary papers to NRC to document this. These papers were received in the Region I office December 16, 1992, and are presently under review by the staff.

Dr. Shankman thanked the licensee representatives for their forthrightness. The meeting was adjourned.