U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Enforcement Conference Report No. 030-17512/90002(DRSS)

Docket No. 030-17512

License No. 34-00[illegible]10 Category G(1) Priority I

Licensee: St. Luke Hospital
Division of Radiation Oncology
Cleveland, OH 44104

Enforcement Conference At: NRC Region III Office, Glen Ellyn, Illinois

Enforcement Conference Conducted: July 31, 1990

Site Inspection Conducted: June 27-29, 1990

Inspector: Wayne J. Slawinski
Senior Radiation Specialist
8-9-90
Date

Reviewed By: George M. McCann, Chief
Nuclear Materials Safety
Section 1
8/10/90
Date

Approved By: Bruce S. Mallett, Ph.D., Chief
Nuclear Materials Safety Branch
8/10/90
Date

Meeting Summary

Enforcement Conference on July 31, 1990 (Report No. 030-17512/90002(DRSS))
Areas Discussed: A review of two therapeutic misadministrations and their apparent causes, the apparent violations and concerns identified during the inspection, the licensee's corrective actions and an overview of the NRC enforcement policy.

DETAILS

1. Conference Attendees

St. Luke's Hospital

J. Jeney, Vice President, Ancillary Services
P. Catanzaro, M.D., Co-Director, Division of Radiation Oncology

Nuclear Regulatory Commission, Region III

C. E. Norelius, Director, Division of Radiation Safety and Safeguards
G. M. McCann, Chief, Nuclear Materials Safety Section 1
W. H. Schultz, Enforcement Coordinator
W. J. Slawinski, Senior Radiation Specialist
J. Cameron, Radiation Specialist

2. Enforcement Conference Summary

An enforcement conference was held in the NRC Region III offices on July 31, 1990. The conference was conducted to discuss two recent therapeutic misadministrations and the findings of a June 27-29, 1990 special inspection at St. Luke's Hospital during which three apparent violations of regulatory requirements were identified. Inspection findings are documented in Inspection Report No. 030-17512/90001(DRSS), transmitted to the licensee on July 26, 1990.

The purpose of the conference was to (1) discuss root and contributing causes of two recent therapeutic (teletherapy) misadministrations; (2) discuss apparent violations and concerns identified during the NRC inspection; (3) discuss the licensee's corrective actions; (4) determine whether there were any aggravating or mitigating circumstances; and (5) obtain other information that would help determine the appropriate enforcement actions.

The licensee did not contest any of the apparent violations and indicated general agreement with the information and concerns delineated in Inspection Report No. 030-17512/90001(DRSS).

The licensee presented a corrective action program focusing on teletherapy treatment quality assurance and reiterated certain of the corrective actions taken shortly after their identification of the misadministration events and prior to the NRC site inspection. Corrective actions taken by the licensee prior to the inspection are described in the aforementioned inspection report. Additional corrective actions developed by the licensee subsequent to the inspection and not reflected in the inspection report consist primarily of procedures that outline and detail specific steps and designation of responsibilities necessary to ensure treatment quality assurance. These p ocedures include the following:

- Description of the Radiation Oncology Department's "Treatment Planning" process.

- Outline of the steps and responsibilities for "Treatment Delivery."

- Checklist of what constitutes an acceptable "Physics Review."

- Description of "Weekly Chart Checks by Physicians" and a checklist of what constitutes an acceptable "Physician Chart Review."

- Treatment "Start Up Check List" for technologists.

- Description of the Radiation Oncology Department's "Acute Radiation Reaction" clinical quality assurance program.

The licensee plans to finalize and implement the above draft procedures during the week of August 6, 1990, develop a revised Division of Radiation Oncology QA Manual that includes the new procedures and subsequently submit the revised QA Manual to the NRC for incorporation into their NRC license. Additionally, the licensee is developing a performance appraisal system for technologists and is considering development of a periodic independent audit to verify QA program implementation. The licensee continues to review therapy technologist and department staffing concerns identified during the inspection.

NRC representatives stated that the licensee's corrective actions appear appropriate and that the modifications planned for their QA program were comprehensive and addressed the recommendations described in the inspection report. NRC representatives stated that Region III recommendations concerning enforcement action would be forwarded to the NRC Office of Enforcement for review. The licensee will be notified in writing of the NRC's proposed enforcement action.