U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Enforcement Conference Report No. 030-09964/94002(DRSS)

Docket No. 030-09964

License No. 13-15882-01

Licensee: The Community Hospital
Munster, Indiana

Enforcement Conference At: NRC Region III Office
801 Warrenville Road
Lisle, Illinois 60532

Enforcement Conference Conducted: June 2, 1994

Inspection Conducted: May 2 and 3, 1994

Inspector: _____ 6/8/94
James L. Cameron
Radiation Specialist
Date

Reviewed By: _____ 6/8/94
B.J. Holt, Chief
Nuclear Materials Inspection
Section 1
Date

Approved By: _____ 6/9/94
Roy J. Caniano, Chief
Nuclear Materials Safety Branch
Date

Meeting Summary

Enforcement Conference on June 2, 1994 (Report No. 030-09964/94002(DRSS))
Areas Discussed: A review of the findings from the May 2 and 3, 1994, inspection, including a discussion of the apparent violations, the accuracy of the facts, causal factors, the corrective actions taken or planned by the licensee, and the NRC Enforcement Policy.

## DETAILS

1. Conference Attendees

The Community Hospital

John Gorski, Director, Ancillary Services
Wayne Wcislo, Director, Nuclear Medicine
Eric Zickgraf, M.S., Radiation Safety Officer
Sue Boulden, Director, Diagnostic and Therapeutic Radiology
Stan Huber, S. A. Huber Consultants

Nuclear Regulatory Commission

Roy J. Caniano, Chief, Nuclear Materials Safety Branch, Region III
Bruce Berson, Regional Counsel, Region III
Jamnes L. Cameron, Radiation Specialist, Region III
Michael LaFranzo, Radiation Specialist, Region III
Robert DeFayette, Director, Enforcement and Investigation Coordination Staff, Region III
Charles Weil, Senior Enforcement Specialist, Region III

2. Enforcement Conference Summary

An Enforcement Conference was held in the NRC Region III office on June 2, 1994, between members of the NRC and The Community Hospital staffs. The conference was held to discuss the findings of an NRC inspection conducted on May 2 and 3, 1994, which identified several apparent violations. NRC inspection findings are documented in Inspection Report No. 030-09964/94001(DRSS), transmitted to the licensee by letter dated May 27, 1994. One apparent violation, which is being considered for escalated enforcement, involved the licensee's failure to establish and implement a written quality management program for all pertinent diagnostic and treatment modalities for which licensed material is used.

The purpose of the conference was to: (1) review the apparent violations; including root and contributing causes; (2) discuss the accuracy of the inspection findings; (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 action.

The licensee did not contest the apparent violations and agreed with the accuracy of the information presented. The licensee described its corrective actions for the apparent violations that were discussed during the conference. In summary, the licensee's corrective actions include: (1) revising its quality management program (QMP) to include all pertinent modalities for which licensed material is used and submitting the QMP to Region III; (2) reviewing the QMP requirements with all authorized users and nuclear medicine technologists;

(3) auditing of each therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either sodium iodide iodine-125 or iodine-131 given in the nuclear medicine department; (4) auditing by a member of the radiation safety committee each quarter of each therapeutic dosage of a radiopharmaceutical, brachytherapy, or remote afterloader procedure performed in the radiation therapy department; (5) revising the forms used to document the results of each QMP audit; (6) requiring that the radiation safety committee perform an audit of the QMP each quarter and annually; and (6) tracking of all incoming and outgoing correspondence between the licensee and the NRC.

During the Enforcement Conference, the licensee provided a written description of its corrective actions. A copy of those corrective actions are attached to this report.

The NRC staff acknowledged the licensee's statements and indicated that they would be considered in the NRC's decision for enforcement action.

3. Concluding Statement

NRC representatives summarized the NRC Enforcement Policy and process and indicated that the licensee will be notified in writing of NRC's proposed enforcement actions.

Attachment: Ltr. dtd. 06/02/94
RE: Corrective actions