Title: ST. MARY MEDICAL CENTER:

FAILURE TO REPORT ALLEGED THERAPEUTIC MISADMINISTRATIONS

Licensee:

St. Mary Medical Center
Hobart and Gary
1500 South Lake Park Avenue
Hobart, Indiana 46342

Docket Nos.: 030-31379; 030-01615

Case Number: 3-90-008

Report Date: June 6, 1991

Control Office: OI:RIII

Status: CLOSED

Reported by:

Richard Paul, Senior Investigator
Office of Investigations
Field Office, Region III

Reviewed and Approved by:

Eugene T. Pawlik, Director
Office of Investigations
Field Office, Region III

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DETAILS OF INVESTIGATION

Purpose of Investigation

On April 23, 1990, the Office of Investigations (OI) received a Request for Investigation from the NRC Region III (RIII) Regional Administrator concerning an allegation of failure to report therapeutic misadministrations to the NRC which occurred at St. Mary Medical Center. The investigation was to determine whether licensee management or [redacted] failure to report therapeutic misadministrations to RIII was a willful violation.

Background

On March 28, 1990, RIII received allegations from the Chief of the State of Indiana's Radiological Health Section concerning unsafe brachytherapy treatment of patients at St. Mary Medical Center. On March 30, 1990, RIII performed an unannounced special inspection of the allegations. The inspection disclosed that at least three therapeutic misadministrations occurred that were not reported to the appropriate NRC regional office. RIII determined that the [redacted] was well qualified and knowledgeable in the licensee's administrative controls. Discussions of those administrative controls intended to prevent misadministrations were documented in the Radiation Safety Committee Meeting minutes where [redacted] was present. According to RIII, it was the licensee management's and [redacted] responsibility to identify misadministrations for reporting (Exhibit 1).

Closure Information

On May 14, 1990, the NRC:RIII Regional Administrator requested that the OI investigation be held in abeyance pending review of a claim made by St. Mary Medical Center that the misadministrations had not, in fact, occurred. This review was to be conducted by RIII inspectors and NRC medical consultants (Exhibit 2).

On April 26, 1991, the NRC:RIII Regional Administrator advised OI that the RIII and Headquarters' review concluded that the licensee records were inadequate to determine whether or not misadministrations had occurred. Based upon the staff's conclusion that no misadministrations were identifiable, the Regional Administrator stated that there also no longer existed a regulatory foundation for an OI investigation into an alleged cover-up of misadministration (Exhibit 3).

Based upon OI:RIII's review and evaluation of this information, this investigation is being closed.

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LIST OF EXHIBITS

Exhibit No.	Description
1	Region III Request for Investigation, dated April 23, 1990.
2	Memorandum from DAVIS to Pawlik, dated May 14, 1990, re: Request for Investigation Regarding St. Mary Medical Center.
3	Memorandum from DAVIS to Pawlik, dated April 26, 1991, re: St. Mary Medical Center Referral RIII-90-007.