

DCD/DCB

DEC 24 1992

Saint John's Medical Center
ATTN: James Moore, Vice President
Clinical Services
2015 Jackson Street
Anderson, IN 46014

License No. 13-17793-02
Docket No. 030-19555

Dear Mr. Moore:

This refers to the special safety inspection conducted by James R. Mullauer and Michelle S. Barry of this office on November 24, 1992, of activities authorized by NRC Byproduct Material License No. 13-17793-02 and to the discussion of our findings with you and members of your staff. The inspection was prompted by your notification to our office of the occurrence of a misadministration involving a teletherapy treatment.

The enclosed copy of our inspection report identifies areas examined during the inspection. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, independent measurements, and interviews with personnel. As you are aware, the NRC contracted a medical consultant, Edward B. Silberstein, M.D., to evaluate the medical significance of the misadministration. Dr. Silberstein's report is attached.

Based on the results of this inspection, several concerns were identified relating to the implementation of your Quality Management Program (QMP). These were discussed with you at the conclusion of the inspection. One concern in particular involves an apparent failure to verify the data used for calculation of the treatment dose that subsequently resulted in a misadministration. The NRC's review of this matter and its applicability to the requirements in 10 CFR 35 relative to the Quality Management Program is not complete. Therefore, a decision regarding enforcement will be withheld pending the outcome of our review. No response to this letter is required at this time. You will be advised of our decision in the near future.

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St. John's Medical Center

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In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

Sincerely,

ORIGINAL SIGNED BY W. L. AXFORD

Charles E. Norelius, Director
Division of Radiation Safety
and Safeguards

Enclosure: Inspection Report
No. 030-19555/92001(DRSS)

cc w/enclosure:
Indiana State Board of Health
DCD/DCB (RIDS)

bcc w/enclosure:
J. Lieberman, OE
J. Glenn, NMSS

(yes)
RIII

12/24/92
Mullauer/rr

(yes)
RIII

12/24/92
Barry

(yes)
RIII

12/24/92
Holt

RIII

Caniano

(yes)
RIII

12/24/92
DeFayette

(yes)
RIII

12/24/92
Norelius

ATTN: Jim McEnright

DATE: 1/11/93

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___ OTHER: Returned per your request during telcon w/ Lee McNally today.

NAME: Rick Repetto

PHONE: X 28640

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* NAME: PDR ROOM, PHONE: 708/790-5630
* FROM: ROSE ROZHON, DRSS, RIII

(Xerox Copy)