

IE-07
PUBLIC

MAR 21 1994

Bethesda Hospital
ATTN: William Groneman
Senior Vice President
619 Oak Street
Cincinnati, OH 45206

License No. 34-10921-03
Docket No. 030-02809

Dear Mr. Groneman:

SUBJECT: NRC INSPECTION REPORT NO. 030-02809/94001(DRSS)

This refers to the onsite announced special safety inspection conducted by Mr. Reichhold on December 15, 1993, and Messrs Reichhold and Slawinski on January 27-28, 1994. The inspection was conducted to review an incident involving a dislodged brachytherapy cesium-137 source and a possible related misadministration that occurred on December 8-9, 1993. The inspection also included a limited review of your Quality Management Program (QMP) and the activities associated with use of your High Dose Rate (HDR) remote afterloading brachytherapy device. At the conclusion of the site inspection, the findings were discussed with you and those members of your staff identified in the enclosed report.

Areas examined during the inspection are identified in the report. Within these areas, the inspection consisted of a selective examination of procedures and representative records, observations, and interviews with personnel. The NRC has contracted Judith Stitt, M.D., to evaluate the medical significance of the incident. Dr. Stitt's report will be forwarded to you when it becomes available.

Based on the results of this inspection, seven apparent violations of NRC requirements were identified. These violations are described in Sections 6 through 8 of the enclosed report. Two additional issues were identified, but currently are unresolved. These issues are specific to the reported brachytherapy incident and pertain to the adequacy of your written directive and the determination of whether the incident resulted in a medical misadministration, as defined in 10 CFR 35.2. The apparent violations and unresolved issues are currently under review by the NRC. You will be advised by separate correspondence of our conclusions regarding these matters. Accordingly, no Notice of Violation is being issued at this time for these inspection findings. Be advised, however, that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. No written response is required at this time.

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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.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Original Signed by Roy Caniano for

W. L. Axelson, Director
Division of Radiation Safety
and Safeguards

Enclosure: Inspection
Report No. 030-02809/94001(DRSS)

bcc w/enclosure:
Judith N. Stitt, M.D.
J. Lieberman, OE
J. Goldberg, OGC
R. Bernero, NMSS
D. Serig, NMSS
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RIII ^{YES}
Reichhold/bt
03/ /94

^{YES}
RIII
Slawinski
3/17/94

^{YES}
RIII
Holt
3/16/94

RIII ^{YES}
Car...
3/1/94

RIII
DeFayette
3/2/94

RIII
Axelson
3/1/94