

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

APH 0 5 1994

Docket No. 030-17617 License No. 22-18989-01 EA 93-257

Memorial Hospital ATTN: Clayton R. Peterson President 725 S. Dellwood Street Cambridge, Minnesota 55008

Dear Mr. Peterson:

SUBJECT: RECISION OF PROPOSED IMPOSITION OF CIVIL PENALTY

This refers to your Answer and Reply, dated December 3, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated November 3, 1993. Our letter and Notice described violations which were identified during an NRC inspection conducted on June 24 through July 13, 1993. To emphasize the need for development and use of a written directive for the administration of sodium iodide 125 or 131 in quantities greater than 30 microcuries and to emphasize the need for management and the Radiation Safety Officer to take a more active and responsible roly in execution of the radiation safety and quality management programs, a civil penalty of \$2,500 was proposed.

In your December 3, 1993 responses, you admitted the violations, but requested mitigation or remission of the proposed civil penalty based on your prompt and comprehensive corrective actions. Additionally, in support of your request, you indicated that the appropriate characterization of the Quality management Program (QMP) violations is Severity Level IV rather than Severity Level III because: 1) an authorized user was always present for each administration of iodine 131 in quantities greater than 30 microcuries; 2) no misadministrations had occurred; and 3) the two registered technologists involved and the Radiation Safety Officer (RSO) contributed to authoring the QMP so they were knowledgeable about aspects of your QMP.

After consideration of your responses, we have concluded that the corrective actions you had completed by July 29, 1993, for your QMP violations and in response to the NRC confirmatory action letter issued July 9, 1993, were adequate and timely in response to the violations identified in the August 2, 1993 inspection report.

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Further, upon reconsideration of the inspection findings and the information presented in your December 3, 1993 responses, the NRC staff has determined that the QMP violations are more appropriately categorized at Severity Level IV instead of a Severity Level III Problem and is amending the record of this enforcement action accordingly. The level of the regulatory significance is reduced given that: 1) an authorized user was always present at administration; 2) there had been no misadministrations; 3) the two registered technologists involved and RSO were the authors of the plan; and 4) you were using a worksheet describing the prescribed dosages prior to administering iodine 131.

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Civil monetary penalties are not normally assessed for violations that are categorized at Severity Level IV and, therefore, the civil penalty proposed in the November 3, 1993 NRC letter is being rescinded. As a result, your arguments regarding mitigation of the civil penalty amount are not further addressed herein.

Mowever, since your staff was unaware that written directives were necessary for administering iodine 131 and because quarterly reviews of your QMP had not been performed, additional management attention and involvement in the QMP appears to be warranted. In addition, you should note that any further failure to comply with the QMP on the part of Memorial Hospital may be subject to escalated enforcement action, such as the issuance of a civil monetary penalty or an order to modify, suspend, or revoke your NRC license which authorizes you to possess byproduct materials for medical use. The effectiveness of your corrective actions will be reviewed during a future inspection.

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

Sincerely,

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James Lieberman, Director Office of Enforcement

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