



Healthcare Group

02/1/93

December 29, 1993

U.S. Nuclear Regulatory Commission
Region III
John B. Martin
Regional Administrator
801 Warrenville Road
Lisle, IL 60532-4351

RE: Bronson Methodist Hospital

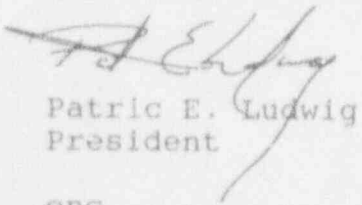
Dear Sir:

We received a letter dated November 30, 1993 outlining the results of our Quality Management Program inspection. This notice of Violation references NRC INSPECTION REPORT NO. 303-02146/93001.

Attached is our REPLY TO A NOTICE OF VIOLATION as requested in the notice. A copy of this response is also being forwarded to U.S. Nuclear Regulatory Commission, Document Control Desk, Washington, D.C., as requested.

Please contact us if there are any further clarifications regarding our response.

Sincerely,


Patric E. Ludwig
President

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One Healthcare Plaza
Kalamazoo, Michigan 49007
616/341-6000

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PDR ADOCK 03002146
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Reply to a Notice of Violation

The following reply is in response to the Notice of Violation, NRC Inspection Report No. 030-02146/93001 dated November 30, 1993.

- A. Written directives were not signed by an authorized user.
 - 1. At the time it was believed that the authorized user did not need to sign personally.
 - 2. The Q.M.P. has been changed to require that all written directives be signed by an authorized user personally.
 - 3. No I-131 doses will be administered without a proper written directive.
 - 4. Full compliance was achieved at the time of the inspection.

- B. Failure to follow up a verbal change with a revised written directive.
 - 1. This was an oversight by the authorized user. Since the authorized user made the change, administered the dose and dictated the change into the chart notes.
 - 2. The Q.M.P. has been revised and approved changes by the NRC after its review.
 - 3. All authorized users have been made aware of the requirements.
 - 4. Full compliance was achieved at the time of inspection once the problem was identified.

- C. Annual reviews of the Q.M.P. was not performed within the 12 months.
 - 1. The audit was performed late.
 - 2. The audit has been performed both for 1992 and 1993 through November.
 - 3. The Q.M.P. has been revised and reviewed by the NRC.
 - 4. Full compliance was achieved in November, 1993.