



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
788 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

November 7, 1991

DES

Docket No. 030-13891
License No. 48-18578-01
EA 91-138

Watertown Memorial Hospital
ATTN: Leo Bargielski
President
125 Hospital Drive
Post Office Box 290
Watertown, WI 53094-3384

Dear Mr. Bargielski:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$6,250
(INSPECTION REPORT NO. 30-13891/91001)

This refers to the routine inspection at the Watertown Memorial Hospital, conducted on September 26, 1991, and authorized by NRC License No. 48-18578-01. The report documenting this inspection was sent to you on October 25, 1991. As a result of the inspection, violations of NRC requirements were identified, and on October 31, 1991, an enforcement conference was held in the Region III office between you and other members of your staff, and Mr. William L. Axelson, Deputy Director, Division of Radiation Safety and Safeguards and other members of the NRC staff.

The NRC has determined that a number of violations of NRC requirements occurred under the Byproduct Material License issued to Watertown Memorial Hospital. The violations, which are described in the enclosed Notice of Violation, include, but are not limited to, the periodic failure to: establish procedures for the receipt of radioactive materials during off-duty hours; perform the daily constancy and the quarterly linearity tests of the dose calibrator and record certain specified information pertaining to the tests; train personnel; survey areas where radioactive materials are used and stored; and perform annual reviews of the radiation safety program. These violations, taken collectively, represent a significant breakdown in the control of NRC licensed activities at Watertown Memorial Hospital. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1991), the violations are classified in the aggregate as a Severity Level III problem.

The root causes of the violations and the subsequent corrective action were discussed during the October 31, 1991, enforcement conference. The NRC recognizes that corrective actions have been initiated and acknowledges the additional information regarding corrective actions you telefaxed to us on November 6, 1991. The major factor contributing to the violations appeared to

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be a lack of management support and oversight of the NRC licensed program and a lack of leadership by those responsible for overseeing the radiation safety program, including the Radiation Safety Committee and the Radiation Safety Officer.

The NRC license issued to Watertown Memorial Hospital entrusts responsibility for radiation safety to the management of the hospital; therefore, the NRC expects effective management and oversight of its licensed programs. Incumbent upon each NRC licensee is the responsibility to protect the public health and safety, including the health and safety of the employees, by assuring that all requirements of the NRC license are met and any potential violation of NRC requirements is identified and expeditiously corrected. To have allowed these violations of NRC requirements to occur and go undetected and uncorrected demonstrates that ineffective and insufficient management oversight of the implementation of the radiation safety program exists at Watertown Memorial Hospital. While no single violation represents a significant health or safety concern, the number and scope of the violations indicate that a significant breakdown exists in the implementation of your radiation safety program. Had proper training been provided to the personnel responsible for implementing the day-to-day radiation safety program, and if routine, comprehensive program audits had been conducted, many of these violations may not have occurred.

To emphasize the need for effective management and oversight of NRC licensed activities, I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$6,250 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is \$2,500. The civil penalty adjustment factors in the Enforcement Policy were considered and the amount of the civil penalty was escalated 50 percent since the NRC identified the violations. The amount of the civil penalty was increased an additional 100 percent for the prior notice of similar events provided to Watertown Memorial Hospital by NRC Information Notice No. 90-71. That Information Notice discussed various failings in exercising management oversight and control of radiation safety programs, including case histories where annual reviews by the Radiation Safety Committee were not done and where the fundamental program deficiency was the lack of sufficient time and attention to the radiation safety program by the Radiation Safety Officer. In addition, the Information Notice indicated the NRC expected the licensee to distribute the Information Notice to hospital management and urged senior managers to carefully read the information contained in the Notice to consider actions to prevent problems from occurring at their facilities.

Your corrective actions were sufficient to return Watertown Memorial Hospital to compliance with NRC requirements with one exception; you did not propose or implement sufficient corrective action concerning the receipt of radiopharmaceuticals during off-hours. At the enforcement conference you proposed to continue to allow representatives of the nuclear pharmacy access to your radiation restricted area during off-hour; without the presence of a hospital representative. The November 6, 1991, telefax appears to indicate that this problem has been corrected. Therefore, on balance, an adjustment to the

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amount of the civil penalty for the licensee's corrective actions was not made. On the whole, the past regulatory performance of Watertown Memorial Hospital has been good with only one violation in each of the two previous inspections. However, the number and scope of the violations disclosed during the September 26, 1991, inspection indicates that your performance significantly deteriorated since the previous NRC inspection. Therefore, no adjustment to the amount of the base civil penalty was made for your past good performance. The remaining factors in the enforcement policy were also considered and no further adjustment to the base civil penalty is considered appropriate.

You are required to document your response to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, please ensure that you described the actions you have taken to strengthen the management and oversight of your NRC licensed program. In addition to your specific response to the violations, please also address the actions you have implemented or plan to take to ensure timely and lasting improvement in your radiation safety program. You should address the management of the program and any improvements needed in the procedures and practices to achieve and maintain compliance with NRC requirements and license conditions, including internal or external audits to assess the effectiveness of your program.

In addition to the violations described in the enclosed Notice, two other apparent violations of NRC requirements were discussed at the enforcement conference. With the information you presented at the enforcement conference, or will obtain in the very near future, the two apparent violations have been withdrawn. Those apparent violations were:

- Contrary to the requirements of 49 CFR 173.475(i), it was believed that you did not examine the surfaces of shipping packages for contamination. At the enforcement conference, you presented information indicating that such examinations were performed.
- Contrary to the requirements of 10 CFR 35.70(f), you did not conduct weekly surveys for contamination so as to be able to detect contamination of each wipe sample of 2,000 disintegrations per minute, as the wipe test samples were analyzed with your nuclear medicine gamma camera. And, the camera was not sufficiently sensitive to detect 2,000 disintegrations per minute. At the enforcement conference, you stated that you believed the nuclear medicine gamma camera could detect 2,000 disintegrations per minute, and planned to perform tests within the next week to demonstrate that capability. Please forward the results of those tests for our review and evaluation to determine if further action by the NRC is required.

After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Watertown Memorial Hospital

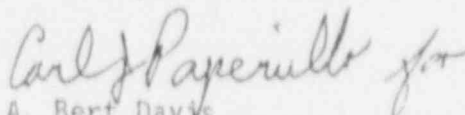
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In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,



A. Bert Davys
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
DCD/DC6 (RIDS)

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