DCD/DCB (RIDS)

November 23, 1990

Docket No. 030-03444
License No. 48-04193-01
EA No. 90-181

Milwaukee County Medical Complex
ATTN: Ms. Julie Hanser, FACHE
Hospital Administrator
8700 West Wisconsin Avenue
Milwaukee, WI 53226

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY-$3,750
(NRC INSPECTION REPORT NO. 030-03444/90001)

This refers to the routine safety inspection conducted on September 26 through 28, 1990 at the Milwaukee County Medical Complex. During the inspection, violations of NRC requirements were identified by the NRC inspectors, and on October 29, 1990, an enforcement conference was held in the Region III office between you and other members of your staff, and Mr. A. Bert Davis, and other members of the NRC staff. A copy of the inspection report was mailed to you on October 25, 1990, and a copy of the enforcement conference report was sent to you on November 21, 1990.

The violations, which are described in the enclosed Notice of Violation, include: (1) violations associated with the brachytherapy program, (2) violations associated with Radiation Safety Committee (RSC) administrative procedures, (3) diverse violations not otherwise categorized, and (4) one violation specifically dealing with lack of management attention.

Additionally, we identified four areas of concern that were discussed during the enforcement conference. Among these: (1) There are questions concerning the adequacy of the Radiation Safety Office staffing level. (2) The Radiation Safety Committee granted "semi-broad-scope" authorizations to users for various isotopes which permitted an applicant to use materials not requested in the application. (3) Documentation of survey instrument calibrations was confusing and poorly maintained such that licensee personnel had difficulty in interpreting it. (4) The brachytherapy source storage safe was not routinely locked, and maintenance personnel had access to the room where the safe was located. Additionally, the brachytherapy sources remained in the transport cart, in this same room, for extended periods of time before being surveyed and returned to the manufacturer. (5) There appeared to be inadequate coordination and communication between the user physicians and the RSO's office to ensure accountability of the brachytherapy sources.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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As a holder of a broad-scope license for use of byproduct material, you are granted the authority to name and train your own users. The proper functioning of the Radiation Safety Officer (RSO) and Radiation Safety Committee (RSC) is critical in ensuring that licensed activities are being carried out with radiation safety in mind and in accordance with all applicable requirements. The number of violations and the lack of management control exercised over your program which allowed these violations to occur and continue undetected and uncorrected are of great concern to the NRC. As a result of these concerns, a Confirmatory Action Letter (CAL RIII-90-20) was issued to you on October 12, 1990 confirming your commitment to immediately initiate corrective actions regarding certain elements of your radiation safety program. Your actions in regard to the CAL were briefly discussed during the enforcement conference. We will pursue any additional measures under separate correspondence.

These violations, if considered individually, would normally be classified at Severity Level IV. However, these violations collectively indicate a lack of management oversight and attention to your radiation safety program. If adequate attention and oversight of licensed activities had been provided, these violations should not have gone undetected and uncorrected until the NRC inspection, and may not have occurred. These violations demonstrate the need for the Medical Complex management to exercise greater control over the conduct of licensed activities to ensure that the RSC and the RSO are aggressively monitoring and evaluating licensed activities within the Medical Complex. It is ultimately the responsibility of management to assure that these activities are conducted safely and in accordance with the terms of your license. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1990), 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 29, 1990 enforcement conference. The major factors contributing to the violations appeared to be that the RSO was not effectively implementing the commitments of your license and the applicable NRC regulations; and that management, including the RSC, did not provide adequate program oversight.

The NRC is particularly concerned that you did not have in place a viable system to ensure that the radiation safety program functioned properly. The NRC holds management responsible for ensuring the safe performance of licensed activities and adherence to NRC requirements. Although the RSO and the RSC are assigned radiation safety responsibilities, management retains the overall responsibility to assure that radiation safety activities are performed in accordance with both internal procedures and NRC requirements. Management must support and monitor the Radiation Safety Programs and licensee staff to make sure they have adequate resources and are implementing all radiation safety requirements. NRC expects management to be aware of the requirements and the responsibilities of the NRC license.

To emphasize the need for additional management oversight of licensed activities on the part of the Medical Complex management, the RSC and the RSO,

I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of $3,750 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is $2,500. The escalation factors in the Enforcement Policy were considered and 50 percent escalation was considered appropriate in that the NRC identified all of the violations. While your corrective actions are adequate, they were undertaken after NRC issued a Confirmatory Action Letter, and they did not focus extensively on the root cause issues concerning lack of control and involvement on the part of the RSO and management above the RSO; therefore, mitigation based on this factor is not appropriate. The other escalation and mitigation factors in the Policy were considered and no further adjustment to the base civil penalty was considered appropriate.

We wish to emphasize that a license to use byproduct material is a privilege granted by the NRC, and any recurrence of a significant violation or problem may result in further escalated action, such as higher civil penalties, or modification, suspension, or revocation of your license.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. 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.

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.

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, PL 96-511.

Sincerely,

A. Bert Davis
Regional Administrator

Enclosures:
1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Inspection Report No. 030-03444/90001

cc w/enclosures:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of Wisconsin

OE	D:OE	(Received via FAX)		
JDelMedico	JLieberman			
11/15/90	11/19/90			
RIII	RIII	RIII	RIII	RIII
Lougheed/db	Norelius	Pederson	Paperiello	Davis
11/20/90	11/20/90	11/21/90	11/23/90	11/23/90

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