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July 17, 1987

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Docket No. 030-18979
License No. 34-19616-01
EA 87-113

St. Luke's Radiologists, Inc.
ATTN: Mr. David Appel
Associate Vice President
11211 Shaker Blvd
Cleveland, OH 44104

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY
NRC INSPECTION REPORT NO. 030-18979/87001(DRSS)

This refers to a special inspection conducted on June 3 and 4, 1987, at St. Luke's Radiologists, Inc., in response to a teletherapy misadministration that your staff identified on June 17, 1986 and reported to the NRC on May 27, 1987. The misadministration apparently occurred as a result of a technologist's failure to carefully review the patient's dose computation sheet, thereby allowing an excessive dose to be administered. The inspection report was sent to you on June 18, 1987. During the inspection, one violation of NRC requirements was identified. The results of the inspection were discussed on June 30, 1987, during an enforcement conference in the NRC Region III office among you and others of your staff and Mr. C. J. Paperiello and members of the NRC Region III staff.

After considering the violation described in the enclosed Notice as well as additional information obtained during the June 30, 1987 enforcement conference, we have concluded that a significant management oversight resulted in failure to report the therapy misadministration to the NRC on a timely basis. In fact, the misadministration was reported to the NRC almost a year after it occurred. The NRC relies on licensee management to implement effective programs which ensure that licensed activities are conducted in accordance with regulatory requirements. In this instance, there was no effective program to ensure that a medical therapy misadministration was reported on a timely basis. Also, it appears there was a significant breakdown in communication among the Medical Therapy Staff, the Radiation Safety Officer and the Senior Administrative Staff. We acknowledge that when the Radiation Oncology Staff became aware of the misadministration, approximately one month after the final patient treatment, it did take appropriate actions to notify the patient and the patient's referring physician; however, the NRC was not notified, as required.

The NRC requires that a therapy misadministration be reported. This information is used by the NRC to identify its cause, to ensure timely corrective action, to ensure timely and proper followup medical care of the patient, and to prevent recurrence. The NRC also uses this information to identify generic problems

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that may be attendant with misadministration problems. When such situations (e.g., equipment malfunctions) are identified, the NRC notifies licensees so that prompt action may be taken by them to avoid the same problem.

To emphasize the importance of prompt identification and reporting of medical therapy misadministrations, I have been authorized, after consultation with the Director, Office of Enforcement, and Deputy Executive Director for Regional Operations, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of One Thousand Two Hundred and Fifty Dollars (\$1,250) for the violation described in the enclosed Notice. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1987) (Enforcement Policy), the violation described in the enclosed Notice has been categorized at Severity Level III. The base civil penalty for a Severity Level III violation is \$2,500. The NRC Enforcement Policy allows for reduction of a civil penalty under certain circumstances. In this case the base civil penalty has been reduced 50 percent for your prior good performance. Full mitigation is not warranted because of the duration of the violation.

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, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with Section 2.790 of the NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, 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, Pub. L. No. 96-511.

Sincerely,

*Original signed by
A. Bert Davis*

A. Bert Davis
Regional Administrator

Enclosure: Notice of Violation
and Proposed Imposition of
Civil Penalty

RIII
[Signature]
Harris

RIII
WMS
Schultz
7-16-87

RIII
[Signature]
Papariello
7/16/87

RIII
[Signature]
Davis
7/16

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