

May 15, 1997

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Carmen Santin  
Associate Vice President, Operations  
Fairview Health System  
2609 Franklin Blvd.  
Cleveland, OH 44113

SUBJECT: NOTICE OF VIOLATION DATED APRIL 4, 1997

Dear Ms. Santin:

This acknowledges receipt of your letter dated April 11, 1997, in response to our letter dated April 4, 1997, transmitting a Notice of Violation.

Your response to the violations did not include all required information, as outlined in the Notice of Violation. Specifically, the response to Violation No. 1 did not include the "reason for the violation" and "the date when full compliance will be achieved." Your response to Violation No. 2 likewise did not include the reason for the violation, nor did the corrective actions fully address the problem.

Based on a May 2, 1997 telephone conversation between Wayne Slawinski of my staff and Frederick Urban, we understand that Violation No. 1 occurred because your staff misinterpreted the written directive requirements of 10 CFR 35. Full compliance for this violation was achieved on February 25, 1997. Violation No. 2 occurred because it was assumed that extending the dose calibrator linearity test to a dose of approximately 30 millicuries was adequate due to the unit's statistical reliability. We further understand that beginning April 11, 1997, dose calibrator linearity tests will extend over the range of its use to include the highest dosage that will be administered to a patient. This range may extend beyond 100 millicuries in some instances.

If our understanding as set forth above is incorrect, please notify Wayne Slawinski or John Madera at (630) 829-9500 immediately.

We have reviewed your corrective actions which except as clarified above, appear to be adequate. We have no further questions at this time. These corrective actions will be examined during a future inspection.

Sincerely,  
Original Signed by Roy J. Caniano

Roy J. Caniano, Acting Director  
Division of Nuclear Materials Safety

License No. 34-01869-01  
Docket No. 030-02690



bec w/ltr dtd 4/11/97: PUBLIC

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NAME	WSlawinski:brt	<input checked="" type="checkbox"/>	JMadera	<input checked="" type="checkbox"/>	RJCaniano	<input checked="" type="checkbox"/>			
DATE	05/13/97	<input checked="" type="checkbox"/>	05/14/97	<input checked="" type="checkbox"/>	05/14/97	<input checked="" type="checkbox"/>			

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# **FAIRVIEW** **HEALTH SYSTEM**

## **LUTHERAN HOSPITAL**

2609 Franklin Boulevard  
Cleveland, Ohio 44113  
(216) 696-4300

April 11, 1997

U.S. Nuclear Regulatory Commission  
Region III  
ATTN: Regional Administrator  
801 Warrensville Road  
Lisle, IL 60532-4351

RE: Response to Notice of Violation  
NRC License #34-01869-01  
Docket #030-02690

To Whom It May Concern:

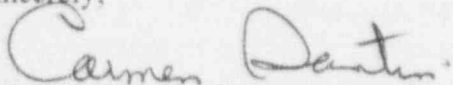
The following correspondence is in response to the Notice of Violation letter dated, April 4, 1997, regarding the inspection conducted, February 24-25, 1997, at our Franklin Boulevard facility (Lutheran Hospital).

In order, our responses are as follows:

1. All In-patient diagnostic studies utilizing I-131 will have a written directive prepared by and signed by an authorized user. This written directive will include the isotope, activity and route of administration. Chart orders will not be recognized as a valid order. It must also be noted that better than 90% of In-patient radioiodine studies are performed utilizing I-123, not I-131.
2. From this point forward, all activity linearity evaluations will be performed using a minimum dose of 100 milicuries.

Any questions regarding this correspondence may be directed to Frederick Urban at (216) 982-1110 at any time.

Sincerely,



Carmen Santin  
Associate Vice President, Operations



CS/ds  
CIRCLE OF CARE

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