NOTICE OF VIOLATION

Department of Veterans Affairs Medical Center
Buffalo, New York

Docket No. 030-02618
License No. 31-00786-02

During an NRC inspection conducted on June 3, 1997, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," the violation is listed below:

10 CFR 35.25(a)(2) requires, in part, that each licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, shall require the supervised individual to follow the written quality management procedures established by the licensee.

(1) Section 3.E.1 of the licensee's written quality management procedure dated April 28, 1997, requires that the technologists read the written directive before ordering, preparing, or administering the radiopharmaceutical.

Contrary to the above, on May 9, 1997, a technologist did not read the written directive before preparing or administering the radiopharmaceutical. Specifically, on that date, a technologist assayed and administered to a patient a 54 microcurie iodine-131 dose when the written directive required that a 5 millicurie iodine-131 dose be administered.

This is a Severity Level IV violation (Supplement VI).

(2) Section 3.E.5 of the licensee's written quality management procedure dated April 28, 1997, requires that the dose calibrator assay be verified with the dosage listed on the written directive and that the individual measuring the dose and the individual verifying the measurement of the dose sign the written directive.

Contrary to the above, on May 9, 1997, the dose calibrator assay was not verified with the dosage listed on the written directive. Specifically, on that date, no individual verified the measurement of the dose because the individual who measured the dose administered the dose before the measurement could be verified.

This is a Severity Level IV violation (Supplement VI).

The NRC has concluded that information regarding the reason for the violation, and the corrective actions taken and planned to correct the violation and prevent recurrence, is already adequately addressed in the May 28, 1997 response to Confirmatory Action Letter 1-97-018. However, you are required to respond to the provisions of 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).