October 13, 1989

Docket No. 030-02611 License No. 31-00032-04 EA 89-165

Veterans Administration Medical Center ATTN: Sanford Garfunkel, Director First Avenue at East 24th Street New York, New York 10010

Gentlemen:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$2,500 (NRC Inspection No. 89-001)

This letter refers to the NRC inspection conducted on July 20, 1989 at your facility in New York, New York, of activities authorized by NRC License No. 31-00032-04. The inspection report was sent to you on August 23, 1989. During the inspection, violations of NRC requirements were identified. On September 8, 1989, an enforcement conference was conducted with Mr. John Donnellan, Associate Director, V.A. Medical Center and other members of your staff to discuss the violations, their causes, and your corrective actions.

The violations, which are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty, include, but are not limited to: (1) failure of the Medical Isotopes Committee to approve users of licensed material and to perform the required annual review of the entire radiation safety program; (2) failure to properly secure radioactive material to prevent unauthorized removal; (3) failure to evaluate whole body and extremity radiation exposures of personnel working in restricted areas and failure to evaluate exposures of persons handling millicuric amounts of phosphorous-32; (4) failure to perform proper surveys of radioactive material packages prior to opening; (5) failure to perform dose calibrator constancy checks before assay of patient doses; and (6) storage of food in areas where radioactive materials are stored and used.

The violations are of particular concern to the NRC because of the number of violations, and because two of the violations are repetitive from the previous NRC inspection of your facility in 1987. During that previous inspection (Inspection Report No. 87-001), violations were identified involving failure to properly survey incoming packages containing radioactive material and storage of food in reas where radioactive materials were stored and used. Notwithstanding the NRC issuance of a Notice of Violation for these matters on December 16, 1987, your corrective actions were not sufficiently comprehensive to prevent recurrence.

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Veterans Administration Medical Center 2

These violations, if considered individually, would normally be classified at Severity Level IV or V. However, the violations collectively indicate a lack of management oversight of, and attention to, your radiation safety program. If adequate attention and oversight of licensed activities had been provided, these violations would not have gone undetected until the NRC inspection. These violations demonstrate the need for Medical Center management, the new Radiation Safety Committee, and the Radiation Safety Officer (RSO) to aggressively monitor and evaluate licensed activities occurring within the Nuclear Medicine & Research Services to assure that these activities are conducted safely and in accordance with the terms of your license.

To emphasize this need, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$2500 for the violations 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 (1989) (Enforcement Policy), these violations have been classified in the aggregate as a Severity Level III problem to focus on our underlying concern, namely, a lack of management attention to licensed activities.

The base civil penalty for a Severity Level III violation or problem is \$2,500. The escalation and mitigation factors in the Enforcement Policy were considered and, on balance, no adjustment of the base civil penalty is considered appropriate. Although escalation of the base civil penalty is warranted since the violations were identified by the NRC, this factor was offset by your prompt and extensive corrective actions. These corrective actions included the proposed expansion of the radiation safety staff to provide independent program surveillance and oversight, as well as reconstitution of the Radiation Safety Committee with more involvement by the Director's Office and Quality Management. Your past performance, which includes five violations in the previous two NRC inspections with two repeat violations identified at this inspection, does not warrant mitigation. The other mitigation and escalation factors were considered and no further adjustment was considered appropriate.

You are required to respond to this letter and the enclosed Notice, 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 take to prevent recurrence. Furthermore, you should describe the actions taken or planned to improve the management oversight of your radiation safety program by the Radiation Safety Officer, the Radiation Safety Committee, and the Medical Center Administration. You do not need to include documents previously submitted at the Enforcement Conference to support the actions taken. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further action is needed to ensure compliance with regulatory requirements. We emphasize that any recurrence of these violations may result in more significant enforcement action.

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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, PL No. 96-511.

Sincerely,

Original Signed P. WILLIAM T. RUSSALL William T. Russell Regional Administrator

Enclosure: Notice of Violation and Proposed Imposition of Civil Penalty

cc w/encl: Public Document Room (PDR) Nuclear Safety Information Center (NSIC) State of New York

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