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October 22, 1996

John Wachs, President
St. Joseph's Hospital
Department of Nuclear Medicine
and Radiation Oncology
5000 West Chambers Street
Milwaukee, WI 53210

SUBJECT: NRC INSPECTION AND NOTICE OF VIOLATION

Dear Mr. Wachs:

This refers to the inspection conducted on August 28-30, 1996 (with continued NRC in-office review through October 9, 1996) at St. Joseph's Hospital, Milwaukee, Wisconsin. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. At the conclusion of the inspection, the findings were discussed with William Artner, Ph.D.

The inspection was an examination of activities conducted under your license as they relate to radiation safety and to compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, independent measurements and observation of activities in progress.

In addition to the above areas, the inspector examined actions described in your letter dated September 17, 1994, regarding apparent violations found during our December 7, 1993 inspection. We have no further questions regarding these matters.

Based on the results of this inspection, the NRC has determined that violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice). A written response is required.

The NRC normally classifies violations associated with improper disposal of licensed material at a Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600 (60 FR 34381; June 30, 1995). However, given the chemical and physical characteristics of the radioactive material that was disposed and the circumstances surrounding the disposal, it is unlikely that the loss resulted in or will result in health and safety concerns. We have, therefore, categorized violation 1 at Severity Level IV. Violations 1 and 2 in particular, but also your poor accountability of: (1) an iridium-192 seed that was unknowingly left in a shielded container for months; and (2) iodine-125 seeds that were initially identified as lost and subsequently identified as implanted in a patient, are indicative of the need to strengthen your oversight and control of all radioactive material to ensure safe use and prevention of improper handling or

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disposal. Any violations involving unauthorized disposal or inadequate oversight and control of licensed material in the future may result in additional enforcement action, including issuance of a civil penalty.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosure, and your response to this letter will be placed in the NRC Public Document Room (PDR). To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction.

Sincerely,

Original Signed by Roy J. Caniano

Cynthia D. Pederson, Director
Division of Nuclear Materials Safety

License No. 48-00537-03
Docket No. 030-03406

Enclosure: Notice of Violation

cc w/encl: B. Burgess

bcc w/encl: PUBLIC

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