UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

April 10, 1997

EA 96-385

Mr. Oliver Crump, Vice President
Ambulatory Services/Clinical Affairs
Washington Hospital Center
110 Irving Street, N. W.
Washington D.C. 20010-2975

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES - $5,000
(NRC INSPECTION REPORT NO. 030-01325/96-001 AND INVESTIGATION REPORT NO. 1-96-035)

Dear Mr. Crump:

This letter refers to the NRC inspection conducted September 17 through 26, 1996, as well as the subsequent investigation by the NRC Office of Investigations (Oi). During the inspection, apparent violations of NRC requirements were identified. A copy of the NRC inspection report was sent to you on November 8, 1996. A copy of the synopsis of the OI investigation was sent to you on January 15, 1997. On January 31, 1997, a predecisional enforcement conference was conducted with you and other members of your staff to discuss the apparent violations, their causes, and your corrective actions. A copy of the Enforcement Conference Report was forwarded to you previously.

Based on the information developed during the inspection, the OI investigation, and information provided during the conference, the NRC has determined that five violations of NRC requirements occurred, as described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The first two violations involve multiple instances of failure to measure employee thyroid burdens (bioassay), and failure to provide adequate training in this area. The remaining three violations are associated with the loss of control of an iodine-125 seed, failure to perform an adequate survey in an attempt to recover the missing radioactive material, and failure to notify the NRC of the loss of the material.

With respect to the violations associated with the failure to perform required bioassays, the NRC is concerned that although the hospital's Radiation Safety Officer (RSO) reminded a number of licensee personnel to measure their thyroid burden within 72 hours of administration of iodine-131, they failed to do so. More importantly, the RSO and Radiation Safety Committee (RSC) chairman were aware of the problem, but apparently failed to recognize the significance of the issue, did not raise the issue in a RSC meeting or to upper management, and did not take prompt, effective corrective action to prevent recurrence of the problem. Individuals involved in the preparation and administration of iodine-131 doses can receive significant uptake of radioactive material which would go undetected if a bioassay is not performed.

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The NRC license issued to Washington Hospital Center entrusts responsibility for radiation safety to the management of the hospital; therefore, the NRC expects effective oversight of its licensed programs. Incumbent upon each NRC licensee is the responsibility of management in general, and the RSC and RSO in particular, to protect the public health and safety by ensuring that all requirements of the NRC license are met and any potential violations of NRC requirements are identified and expeditiously corrected. Collectively, the two violations are of significant regulatory concern because they are indicative of a lack of management attention towards licensed responsibilities. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, these two violations are classified in the aggregate as a Severity Level III problem, and are set forth in section I of the enclosed Notice.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,500 is considered for a Severity Level III problem. Because your facility has been the subject of escalated enforcement action within two years[1] of the date the problem occurred, the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit is warranted for *Identification* because you identified the problem. Your corrective actions include: (1) providing a visual reminder to personnel required to perform bioassays; (2) performing a biweekly check to ensure that required bioassays are completed; (3) enhancing management involvement in the RSC meetings; and (4) developing a planned independent audit of your licensed program. However, credit for your *Corrective Action* is not warranted because your actions were not prompt in that immediate action was not taken to restore safety and compliance once you identified the problem, and the NRC had to take action to focus your evaluative and corrective process in order to obtain comprehensive corrective action. Specifically, even though the RSO reminded personnel to complete bioassays that had not been performed, the problem continued to occur. In addition, the problem was not brought to the attention of management and no measures were put in place to ensure that personnel performed the required bioassays until the NRC identified that corrective action was required.

With respect to the remaining violations, the NRC is concerned about the potential safety consequence of losing licensed material. In this case, the iodine-125 seed that was lost could deliver a significant radiation dose if the seed was in contact with an individual's skin. The NRC is further concerned that even after the NRC informed you that the loss of the seed had to be reported, as of January 31, 1997, the report had not been made apparently due to a lack of understanding of the requirements.

Violations II.A, II.B, and II.C are significant because you have had similar problems in the past. In 1993, you failed to adequately control the use of licensed material which contributed to overexposure of a research associate, and in 1991 you failed to perform an adequate survey and failed to report the loss of 20 millicuries of technetium-99m. In total, the violations represent a significant regulatory concern. Therefore, they are classified in the aggregate in

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[1] A Severity Level III violation with a $2,500 civil penalty was issued on April 28, 1994, for a violation involving a failure to limit the whole body exposure of an individual to 1.25 rem per quarter.

accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600, as a Severity Level III problem, and are set forth in section II of the enclosed Notice.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,500 is considered for a Severity Level III problem. Because your facility has been the subject of escalated enforcement action within two years of the date the problem occurred as noted above, the NRC considered whether credit was warranted for *Identification* and *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. No credit is warranted for identification because the NRC identified the violations. Credit for corrective actions is warranted because your corrective actions were both prompt and comprehensive. These actions include but are not limited to the following: (1) obtaining an additional probe to facilitate surveys; 2) ensuring that all individuals involved in brachytherapy procedures are surveyed prior to leaving the operating room; and 3) installing a portal monitor that monitors all waste leaving the facility.

Therefore, to emphasize the importance of management oversight of licensed activities, the significance of controlling licensed material, and the need for taking prompt action when a problem is identified, I have been authorized after consultation with the Director, Office of Enforcement, to propose civil penalties in the cumulative amount of $5,000 for the Severity Level III problems described above. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection frequency.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements. As noted in our letter to you dated January 15, 1997, OI concluded that several of your employees willfully failed to perform the required bioassays. However, upon review of the evidence, it appears the failures are attributed to a lack of management attention towards licensed responsibilities rather than willful acts on the part of the involved individuals.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be placed in the NRC Public Document Room.

Sincerely,

Hubert J. Miller
Regional Administrator

Docket No. 030-01325
License No. 08-03604-03

Enclosure: Notice of Violation and Proposed Imposition
of Civil Penalties

cc w/encl:
District of Columbia
N. Stewart, Department of Consumer & Regulatory Affairs

Washington Hospital Center

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