WASHINGTON
HOSPITAL
CENTER

DCS

May 5, 1997

James Lieberman, Director
Office of Enforcement
U.S. Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, MD 20852-2738

Subject: Reply to Notice of Violation and Answer to a Notice of Violation (NRC Inspection Report No. 030-01325/96-001 and Investigation Report No. 1-96-035)

Docket No. 030-01325
License No. 08-03604-03
EA No. 96-385

Dear Mr. Lieberman:

Reference letter of April 10, 1997 detailing a notice of violations of NRC regulations by the Washington Hospital Center and requiring the Hospital to reply to the notice. The Hospital's reply is submitted herein as required by that notice. The responses will be itemized categorically in the same order as in the Notice.

1. Violations Associated With Failure to Perform Bioassays

A. The Washington Hospital Center acknowledges that in eleven cases during 1996 involving the administration of therapeutic amounts of I-131 to patients the personnel involved with the administration of the radiopharmaceutical did not receive required thyroid bioassays. Principally, the individuals failing to obtain bioassays were the attending physicians who felt that since they were not in the patient's room during the actual administration the bioassays were not required. On several occassions the technologists who prepared the radiopharmaceutical and administered it failed to get the bioassay.

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B. The physicians who did not obtain the thyroid bioassay claimed they did not know how to operate the bioassay probe, and that was one of the reasons for not getting the bioassay.

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110 Irving Street, NW
Washington, DC 20010-2975

2. Violations Associated With Loss of Control of Licensed Material

A. The WHC acknowledges that on February 22, 1996 a 280 microcurie I-125 seed was lost during a prostate cancer treatment procedure. The loss presumably occurred in the operating room. Surveys of the room during the procedure and after the procedure did not locate the seed, one of 89 that were implanted that day. Apparently, the radiation safety personnel did not completely survey the urologist and the physicist before they left the operating room, although the scrub clothing was monitored along with the rest of the waste from the procedure.

B. Obviously, since the seed was not found, the surveys performed after the apparent loss of the material were inadequate. According to the physicist and urologist, they were not adequately monitored prior to leaving the room.

C. The loss of the seed containing 280 microcuries of I-125 was not reported to the U.S. Nuclear Regulatory Commission within 30 days as required by regulation. The radiation safety officer admits that he misread the table indicating the level of activity that had to be reported.

3. Corrections to Radiation Procedures to Prevent Future Reoccurances of the Violations

A. The Washington Hospital Center radiation safety policy is that bicassays will be performed between 24 and 72 hours after the administration of radioactive iodine compounds (either diagnostic or therapeutic doses). Tighter supervision of the individuals administering the radionuclide will be exercised in the future. Additional training will be given to technologists and physicians regarding the regulatory requirements for the bioassays and the operation of the bioassay equipment. As a note to this matter, this training has been conducted for the past several years. Everyone has been given training in the bioassay requirements and the operation of the equipment used. Additionally, there is always someone in the lab who can set up the instrument for the count, a roughly 5-minute procedure. The radiation safety office has initiated a more intensive oversight of the radioactive iodine administration operation and the concurrent thyroid radioactivity monitoring. Since the inspection in September, 1996, no one has missed a bioassay.

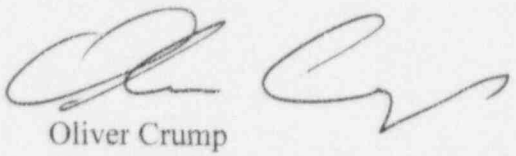
B. The Radiation Safety Officer will be more cognizant in the future concerning reporting requirements of lost sources. Stricter survey procedures that have been implemented should prevent a reoccurrance of the lost implant seed. Additional survey instruments have been obtained and the purchase of others is planned in order to improve detection capability. Radiation safety and radiation oncology personnel have been instructed in the requirement for more stringent monitoring of clothing and personal effects prior to their egress from the operating room following an implant procedure. Since the loss of the radioactive seed the Hospital has implanted over 7000 seeds without

a loss. Tighter survey procedures before, during and after the procedure are being conducted. A more careful monitoring of the radioactive seed inventory has also been implemented.

C. The lost seed incident has been reported to the NRC. The RSO is aware of the fact that the report was late. He is confident that a reporting violation will not happen again. WHC management has been assured that the radiation safety program is in full compliance with NRC Regulations.

3. A check in the amount of $5000.00 is enclosed in payment for the fines associated with the above mentioned violations. If you have any questions concerning this matter please contact me or Dr. Billy Bass at (202) 877-8025.

Sincerely,



Oliver Crump
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