

SEP 24 1996

Docket No. 030-01244
EA No. 96-321

License No. 06-00819-03

Norman G. Roth, Vice President
Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 06504

SUBJECT: INSPECTION NO. 030-01244/96-001

Dear Mr. Roth:

On August 12 and 13, 1996, Neelam Bhalla and Ihor Czerwinskyj of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. Additionally, the inspectors conducted a telephone interview on August 19, 1996 with one of your staff members who was unavailable during the inspection. The inspection was limited to a review of the circumstances surrounding the loss of five iodine-125 seeds at your hospital sometime between March 6, 1996 and July 26, 1996 and reported to the NRC Operations Center on August 6, 1996. The purpose of the inspection was to determine whether activities authorized by the license were conducted safely and in accordance with NRC requirements. The findings of the inspection were discussed with you and other members of your staff at the conclusion of the inspection.

With regard to your iodine-125 brachytherapy program, the following areas were examined during the inspection: ordering, receiving, inventory, security and storage, cleaning and leak testing, surveys of the patient and areas of use, and the incident chronology of the lost sources. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observation of activities in progress.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. A Notice of Violation is enclosed. Each violation is classified at a Severity Level IV violation in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) NUREG 1600 and due to the limited radiological significance in this instance. Similar violations of this type in the future may result in additional enforcement action.

The weaknesses in your implant source inventory procedures, the significance of the issues, and the need for lasting and effective corrective action were discussed with members of your staff at the inspection exit meeting on August 13, 1996.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your

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Norman G. Roth
Yale New Haven Hospital

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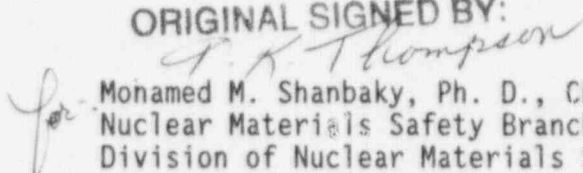
response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Please use the enclosed self-addressed green envelope when you respond to this letter to assist us in the timely processing of your response. In accordance with Section 2.790 of NRC's "Rules of Practice," Part 2, Title 10, Code of Federal Regulations, a copy of this letter and your reply will be placed in the 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. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public. The responses directed by this letter and the accompanying 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 96-511.

Your cooperation with us is appreciated.

Sincerely,

ORIGINAL SIGNED BY:


for Mohamed M. Shanbaky, Ph. D., Chief
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

Docket No.: 030-01244
License No.: 06-00819-03

Enclosures:

1. Notice of Violation
2. NUREG 1600 (Enforcement Policy)

cc w/enclosures:
Michael Bohan, Radiation Safety Officer
State of Connecticut

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Norman G. Roth
Yale New Haven Hospital

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