

OCT 11 1996

Docket No. 030-30561
EA No. 96-300

License No. 06-13022-05

Paul Davern
Associate Hospital Director
University of Connecticut Health Center
263 Farmington Avenue
Farmington, CT 06030-3930

SUBJECT: INSPECTION NO. 030-30561/96-001, NOTICE OF VIOLATION, AND
ACKNOWLEDGEMENT OF YOUR AUGUST 21, 1996 LETTER

Dear Mr. Davern:

On August 14, 1996, Ms. Neelam Bhalla and Mr. Ihor Czerwinskyj of this office conducted a safety inspection at the above address to review the circumstances involving a therapeutic misadministration at your facility which was reported to the NRC on August 7, 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 Cobalt Teletherapy program, the following areas were examined during the inspection: written directives by the authorized user, dose calculations and treatment planning, dose verification checks as required by your Quality Management Program, and the incident chronology of the therapeutic misadministration. Within these areas, the inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observation of activities in progress. The NRC also contracted a medical consultant to review the misadministration.

Based on the results of this inspection, the NRC has determined that a violation of your Quality Management Program requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and is classified at a Severity Level IV violation after careful consideration of the factors involved in this specific instance and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) NUREG 1600. Specifically, the error was limited to one treatment fraction, was identified by the licensee, and immediate corrective actions were initiated. Similar violations of this type in the future may result in additional enforcement action.

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The weaknesses in your Quality Management Program, the significance of the issues, and the need for lasting and effective corrective action were discussed with members of your staff during the inspection on August 14, 1996.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed in your letter dated August 21, 1996. Additionally, we have received your revised Quality Management Program dated August 27, 1996 that includes your corrective actions. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice. Your corrective actions and actions to prevent recurrence will be examined during a future inspection of your NRC licensed program.

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 will be placed in the Public Document Room (PDR).

Your cooperation with us is appreciated.

Sincerely,
Original Signed By:
Mohamed M. Shanbaky

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

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Enclosures:
Notice of Violation
NUREG 1600

cc w/enclosures:
Kenneth Price, Radiation Safety Officer
State of Connecticut w/enc.1

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