

December 19, 1996

Docket No. 030-12239
EA No. 96-187

License No. 20-17131-01

John Gaida, Vice President, Administration
Brigham and Women's Hospital
75 Francis Street
Boston, Massachusetts 02115

SUBJECT: INSPECTION NO. 030-12239/96-001

Dear Mr. Gaida:

On May 13 to 17, 1996, Ihor Czerwinskyj of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you, at the conclusion of the inspection. In addition Daniel Flynn, M.D., NRC's Medical Consultant, has conducted a review of a reported therapeutic misadministration which occurred at your facility on April 27, 1996. Based on further NRC examination, it is concluded that due to patient intervention causing this incident, no misadministration has occurred.

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 and categorizes each violation by severity level in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your 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.

Item A described in the attached Notice of Violation involves the storage and control of licensed material. The violation is classified at a Severity Level IV violation after careful consideration of the factors involved in this specific instance. Specifically, this incident posed a minimal health and safety problem because of the small quantity

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Brigham and Women's Hospital

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of radioactive material (1 millicurie of iodine-125) and the extensive action the licensee took to enhance the security of radioactive materials at its installation. The inspector noted your notice, dated March 1, 1996, to all permit holders, stressing the need to secure all radioactive materials, providing locks for all refrigerators and freezers used to store radioactive materials, and advising all personnel to challenge all unfamiliar personnel who enter the research areas. The inspector noted that the security violation cited in Item A represented an isolated rather than a programmatic weakness in your radiation safety program. Similar violations of this type in the future may result in additional enforcement action.

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,

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

Docket No.: 030-12239
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Enclosure:
Notice of Violation
Inspection Report No. 030-012239/96-001

cc w/enclosure:
Frank Castronovo, Ph. D., Radiation Safety Officer
Commonwealth of Massachusetts

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Distribution: w/encl

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