

SEP 18 1996

Docket No. 030-09062

License No. 20-00742-18

Mr. Malcolm S. Weiner
Vice President of Clinical Support
Services
Beth Israel Hospital
330 Brookline Avenue
Boston, Massachusetts 02215

SUBJECT: INSPECTION NO. 030-09062/96-001

Dear Mr. Weiner:

On August 13, 14, 15 and 16, 1996, Thomas K. Thompson of this office conducted a safety inspection at 99 and 330 Brookline Avenue, Boston, Massachusetts 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. In addition, our inspection examined the activities covered in your correspondence dated November 8, 1995. The findings of the inspection were discussed with you, at the conclusion of the inspection.

Based on the results of this inspection, it appears that your activities were not conducted in full compliance with NRC requirements. Specifically, 10 CFR 35.32(a)(1) requires that a written directive is prepared prior to any administration of quantities greater than 30 microcuries of I-131. The definition of a written directive from 10 CFR 35.2 means an order in writing for a specific patient dated and signed by an authorized user prior to administration. We note that your authorized users are apparently signing the written directives and only failing to date the directive. Other dates entered on these records, such as the assay date, are not sufficient to satisfy the requirement. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG 1600 no Violation is being issued for this inspection finding and no written response is required for this item. An additional item involves the failure to complete the return source log for brachytherapy sources removed from the

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storage room. A Notice of Violation is enclosed and categorizes this 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.

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:

Mohamed Shanbaky, Chief
Medical Branch
Division of Nuclear Materials Safety

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Enclosure:
Notice of Violation

cc w/enclosure:
Rosemary Kennedy, Radiation Safety Officer
Commonwealth of Massachusetts

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