SEP 09 1992

Docket No. 030-00239 License No. 20-03814-14

Massachusetts General Hospital
ATTN: Ms. Maryanne Spicer
Administrative Director of Safety
55 Fruit Street
Boston, Massachusetts 02114

Subject: Special Inspection No. 92-001

On July 23, 1992, Ms. Mary Cahill of this office conducted a special, announced inspection at the above address of activities authorized by the above listed NRC license. The inspection was limited to a review of events surrounding a therapeutic misadministration which occurred from July 8 to July 15, 1992. You reported the misadministration to this office on July 16, 1992. You informed us that a patient receiving palliative treatment with your AECL Theratron 780C teletherapy unit had received a weekly dose of 2070 rads to the ribs rather than the intended dose of 1500 rads. This occurred due to the failure of the therapy physicist to document the appropriate wedge factor in the patient's treatment chart and the subsequent failure to perform adequate quality control checks on the patient's treatment plan. The findings of the inspection were discussed with you and other members of your staff at the conclusion of the inspection.

Based on the results of this inspection, it appears that one of your activities was not conducted in full compliance with NRC requirements. 10 CFR 35.32 requires, in part, that your program policies provide high confidence that final plans of patient treatment and related calculations for teletherapy are in accordance with the respective written directive of the authorized user. Contrary to this, your program policies did not provide high confidence that final plans of patient treatment and related calculations for teletherapy were in accordance with the respective written directive of the authorized user, in that the proper wedge factors were not recorded or verified in the setup and orientation sections of the patient's treatment plan. This contributed to the occurrence of the therapeutic misadministration noted above.

Due to the uncertainty in the implementation status of the Quality Management Program and Misadministration Rule during the period June 26, 1992 to the date of the public announcement of the NRC override, and since the misadministration occurred during this period, we have decided to exercise enforcement discretion in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy)(1992). Therefore, a Notice of Violation is not being issued.

At the conclusion of the inspection, the inspector discussed with you corrective actions which you plan to take to prevent recurrence of a similar violation and the potential misadministration. Based on this discussion and your correspondence dated July 29, 1992, we understand that the box on the treatment plan used for designation of wedge information will accurately be completed by the physics or medical staff and that the radiation therapist will check this information prior to patient treatment. In addition, the physics staff will verify that the wedge information is correct in the setup area of the chart during weekly chart checks and will note on the chart that this has been checked. In addition, instruction on proper procedures for completing and reviewing treatment plans/charts will be given to all staff involved in treating patients. These actions were taken immediately and all involved staff were retrained in this area. These actions will be examined at a future inspection of your licensed program. If our understandings are incorrect, please inform us in writing within 30 days of receipt of this letter.

Please use the enclosed self-addressed green envelope if you respond to this letter to assist us in the timely processing of your response.

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.

Sincerely,

Original Signed By:
Mohamed M. Shanbaky

Mohamed M. Shanbaky, Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts
Rex Woodleigh, Radiation Safety Officer

bcc:
Region I Docket Room (w/concurrences)
John Glenn, NMSS
Dan Holody, RI
Mary Cahill, RI
Judy Joustra, RI

RI:DRSS	RI:DRSS	NMSS
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