APPENDIX A

NOTICE OF VIOLATION

Carlisle Hospital
Carlisle, Pennsylvania 17013

Docket Nos. 030-00472
030-03018
License Nos. 37-02385-01
37-02385-02

During an NRC inspection conducted on February 2 and 3, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

A. 10 CFR 35.22(b)(2) requires that, to oversee the use of licensed material, the Radiation Safety Committee must review, on the basis of safety and with regard to the training and experience standards in Subpart J of 10 CFR Part 35, and approve or disapprove any individual who is to be listed as an authorized user, the Radiation Safety Officer, or a Teletherapy Physicist before submitting a license application or request for amendment or renewal.

Contrary to the above, on multiple occasions, the licensee submitted requests for a license amendment and as of those dates, the licensee's Radiation Safety Committee had not reviewed and approved, on the basis of safety and with regard to the training and experience standards in Subpart J of 10 CFR Part 35, an individual who was named in the requests as the licensee's authorized user. Specifically, on May 12, 1992, the licensee submitted a request for license amendment to include an individual as authorized user on its license, and again on July 14, 1992, the licensee submitted a request for license amendment to include another individual as authorized user on its license and as of those dates the Radiation Safety Committee had not reviewed and had not approved the respective individual to be listed as authorized user. Similarly, on November 24, 1993, the licensee submitted a request for a license amendment to reflect the change of its Radiation Safety Officer, and the new Radiation Safety Officer was not approved by the Radiation Safety Committee.

This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 35.22(a)(2) requires that the Radiation Safety Committee meet at least quarterly.

Contrary to the above, the licensee's Radiation Safety Committee did not meet

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between June 12, 1992 and November 19, 1992, a period in excess of one calendar quarter.

This is a Severity Level IV violation (Supplement VI).

C. 10 CFR 35.32(b) requires, in part, that the licensee develop procedures for and conduct a review to verify compliance with all aspects of the quality management program at intervals no greater than 12 months.

Contrary to the above, as of February 2, 1994, the licensee had neither conducted a review nor developed procedures for conducting a review to verify compliance with the licensee's quality management program.

This is a Severity Level IV violation (Supplement VI).

D. 10 CFR 35.634(a)(1) requires that a licensee authorized to use teletherapy units for medical use perform monthly output spot-checks on each teletherapy unit that include determination of timer constancy and timer linearity over the range of use.

Contrary to the above, the licensee's monthly output spot-checks performed on March 11, 1993, on its teletherapy unit did not include a determination of timer constancy and timer linearity over the licensee's full range of use of up to 7.79 minutes.

This is a Severity Level IV violation (Supplement VI).

E. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of February 2, 1994, individuals who were working in the Nuclear Medicine Suite, a restricted area, had not been instructed in the applicable provisions of the regulations and the conditions of the license. Specifically, the nuclear medicine technologists were not instructed how to check the survey instruments for proper operation with the dedicated check source.

This is a Severity Level IV violation. (Supplement VI)

F. 10 CFR 35.50(e) and 35.50(e)(1) require, in part, that a licensee retain records of daily constancy checks of the dose calibrator for three years unless directed otherwise, and that the records include the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check.

Contrary to the above, as of February 2, 1994, the licensee's records of daily constancy checks of its dose calibrator performed between January 2, 1994 and February 2, 1994 did not include the model and serial number of the dose calibrator.

This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Carlisle Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.