APPENDIX A

NOTICE OF VIOLATION

Elizabeth General Medical Center - West
Elizabeth, New Jersey 07201

Docket No. 030-02437
License No. 29-01600-02

As a result of the inspection conducted on October 23, 1990, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1990), the following violations were identified:

A. 10 CFR 35.60(b) requires that licensees conspicuously label each syringe, or syringe radiation shield that contains a syringe with a radiopharmaceutical and that the label show the radiopharmaceutical name or its abbreviation, the clinical procedures to be performed, or the patient's name.

Contrary to the above, on October 23, 1990, a syringe containing a radiopharmaceutical, had not been labelled as required. Specifically, neither the syringe which contained technetium-99m, nor the syringe shield had been labeled as required.

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

B. 10 CFR 35.21(b)(1) requires, in part, that the Radiation Safety Officer investigate deviations from approved radiation safety practice and implement corrective actions as necessary.

Contrary to the above, on March 6, 1990, the Radiation Safety Officer (RSO) neither investigated deviations from approved radiation safety practice nor implemented corrective actions as necessary when a deviation from approved radiation safety practice occurred. Specifically, the RSO did not investigate the administration of 15 millicuries of Tc-99m (MDP) to a pregnant patient. Determination as to whether the patient was pregnant had not been made prior to administering the radiopharmaceutical, contrary to the licensees established policy and procedure "Protecting The Pregnant Or Potentially Pregnant Patient Who Utilizes Radiological Services."

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

C. 10 CFR 35.204 requires that licensees using molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical determine the total molybdenum-99 concentration in each eluate or extract prior to administering that elution to patients.

Contrary to the above, as of October 23, 1990, the licensee did not determine the total molybdenum-99 concentration in each eluate or extract prior to administering that elution to patients. Specifically, each eluate was not correctly assayed for molybdenum-99 activity in that the manufacturers correction factor had not been applied.

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

D. 10 CFR 35.70(f) requires that a licensee conduct the surveys required by paragraph (e) of this section so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.

Contrary to the above, as of October 23, 1990, the licensee did not conduct surveys so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute. Specifically, surveys intended to meet this requirement were made, but were inadequately evaluated from September 17, 1990 to October 19, 1990, in that the number of disintegrations per minute had not been calculated correctly. The number of counts per minute had been multiplied by the efficiency rather than divided as required.

This is a Severity Level IV. (Supplement IV)

Pursuant to the provisions of 10 CFR 2.201, Elizabeth General Medical Center - West is hereby required to submit to this office within thirty days of the date of the letter which transmitted this Notice, a written statement or explanation in reply, including: (1) the corrective steps which have been taken and the results achieved; (2) corrective steps which will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending this response time.