APPENDIX A

NOTICE OF VIOLATION

Clara Maass Medical Center
Belleville, New Jersey 07109

Docket Nos. 030-02467
070-01404
License Nos. 29-03163-03
SNM-1371

As a result of the inspection conducted on October 24, 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 20.401(c)(1) requires in part that records of individual exposure to radiation and to radioactive material which must be maintained pursuant to the provisions of paragraph (a) of this section and records of bioassays made pursuant to 20.108 shall be preserved until the Commission authorizes disposition.

Contrary to the above, as of October 24, 1990, records of bioassays made pursuant to 20.108 were not preserved until the Commission authorized disposition. Specifically, records of bioassays performed on those who administered therapeutic quantities of liquid iodine-131 to patients were not preserved by the licensee.

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

B. Condition 16 of License No. 29-03163-03 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated December 18, 1984.

1. Item No. 7 of this application requires that the responsibilities, duties and meeting frequency of the Radiation Safety Committee (Medical Isotope Committee) be as described in Appendix B of Regulatory Guide 10.8 (Rev. 1).

Appendix B of Regulatory Guide 10.8 requires the Radiation Safety Committee meet as often as necessary to conduct its business but not less than once in each calendar quarter.

Contrary to the above, as of October 24, 1990, the Radiation Safety Committee met to conduct business less than once in each calendar quarter. Specifically, the Radiation Safety Committee only met two times per year.

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

2. Item No. 10 of this application requires that dose calibrators be calibrated in accordance with procedures contained in Appendix D, Section 2, of Regulatory Guide 10.8. (Rev. 1).

   a. Item A of Appendix D requires that the dose calibrator accuracy be tested at installation and annually thereafter.

      Contrary to the above, as of October 24, 1990, the dose calibrator accuracy had not been tested annually.

   b. Item C of Appendix D requires that the dose calibrator daily constancy check include an indication of the predicted activity of each source used based on decay and a determination of variation greater than ±5% from the predicted activity.

      Contrary to the above, as of October 24, 1990, the dose calibrator daily constancy check did not include a determination of variations greater than ±5% from the predicted activity. Specifically, this determination had not been made since November 1988.

   These are Severity Level IV violations. (Supplement VI)

C. 10 CFR 35.404 requires that immediately after removing the last temporary implant source from a patient, the licensee shall make a radiation survey of the patient with a radiation detection survey instrument to confirm that all sources have been removed and to retain a record of patient surveys for three years.

   Contrary to the above, as of October 24, 1990, the licensee did perform the required patient surveys but did not retain a record of the patient surveys for three years. Specifically, records for six temporary implants, which were performed between March 1, 1990 and August 31, 1990, were not retained.

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

Pursuant to the provisions of 10 CFR 2.201, Clara Maass Medical Center 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.