APPENDIX A

NOTICE OF VIOLATION

Irvington General Hospital
Irvington, New Jersey 07111

Docket No. 030-02508
License No. 29-07987-02

As a result of the inspection conducted on September 13, 1985, and in accordance with the NRC Enforcement Policy (10 CFR 2, Appendix C), the following violations were identified:

A. 10 CFR 71.5(a) requires that no licensee deliver any licensed material to a carrier for transport without complying with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 40 CFR Parts 170-189.

49 CFR 172.203(d)(iii)(IV) and (V) required that the description for a shipment of radioactive material include the activity contained in each package in terms of curies, millicuries or microcuries, the category of label applied to each package and the transport index assigned to each package.

Contrary to the above, on February 25, 1985 and May 31, 1985 a Mo-99 generator was shipped back to its distributor and the licensee did not indicate the activity, the category of label or the transport index on its shipping papers.

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

B. Condition No. 16 of License No. 29-07987-02 requires that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated January 10, 1980, and letter dated November 20, 1980.

1. Item No. 7 of this application requires that the medical isotopes committee perform its duties in accordance with Appendix B, Regulatory Guide 10.8, Revision 1, 1980

Appendix B of Regulatory Guide 10.8 requires that the Medical Isotopes Committee meet as often as necessary but not less than once in each calendar quarter.

Contrary to the above, the licensee's Medical Isotopes Committee met on April 4 and September 5 in 1982, on June 19 in 1983, did not meet in 1984, and met on March 15 and August 16 in 1985 which is less than once in each calendar quarter.

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

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.

Item C.8 of Appendix D, Section 2 requires that the dose calibrator be checked daily for instrument constancy and that variations of greater than ± 5% from the predicted activity require instrument repair or adjustment.

Contrary to the above, from January 2, 1985 to March 5, 1985, variations from the predicted activity were between 5% and 10% and the required repair or adjustment was not performed.

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

3. Item No. 2, Calibration of Dose Calibrator and Standard Source, of letter dated November 20, 1980 requires that the dose calibrator will be checked annually for instrument accuracy using Co-57, Co-60 and Cs-137 sources.

Contrary to the above, the dose calibrator was checked using only Co-57 and Cs-137 in 1983 and as of September 13, 1985 had not been checked with all three sources for more than one year.

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

Pursuant to the provisions of 10 CFR 2.201, Irvington General Hospital 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.