APPENDIX A

NOTICE OF VIOLATION

Columbus Hospital
Newark, New Jersey 07107

Docket No. 030-09949
License No. 29-07213-03

As a result of the inspection conducted on August 25 and 26, 1992, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1992), the following violations were identified:

A. 10 CFR 20.201(b) requires, in part, that each licensee make such surveys as may be necessary to comply with all sections of Part 2 . As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive material or other sources of radiation under a specific set of conditions.

10 CFR 20.311 requires that each shipment of radioactive waste to a licensed land disposal facility must be accompanied by a shipment manifest that contains, in part, radionuclide identity and quantity.

Contrary to the above, as of August 26, 1992, the licensee did not make the necessary surveys to comply with Part 20 in that adequate surveys were not made to assure compliance with 10 CFR 20.311. Specifically, the licensee did not properly evaluate the quantity of radioactive material in packages from the Pathology Department prior to transfer for disposal to a licensed land disposal facility.

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

B. 10 CFR 35.21(b)(2)(v) requires, in part, that the Radiation Safety Officer establish and implement written policy and procedures for using byproduct material safely. In the letter dated June 11, 1990, the established written policy and procedures in Appendix I of Regulatory Guide 10.8, Revision 2, "Safe Use of Radiopharmaceuticals" was incorporated as the standard procedure for using byproduct material safely.

Appendix I, Rule 14 of Regulatory Guide 10.8 requires, in part, that each patient dose be assayed in a dose calibrator before it is administered and that the dosage not be used if it is more than 10 percent off from the prescribed dose.



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Contrary to the above, the established procedure for using by product materials safely was not followed. Specifically, patient doses assayed in a dose calibrator before administration, were used, on many occasions, when measurements indicated that the assayed doses were greater or less than 10 percent of the prescribed dose. For example, on July 29, 1992, three 25 millicurie doses of technetium-99m medronate diphosphate were prescribed and 29.2, 28.8, and 29.1 millicuries respectively, were administered to three patients.

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

Pursuant to the provisions of 10 CFR 2.201, Columbus 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.