NOTICE OF VIOLATION

Syncor Corporation
Akron, Ohio

Docket No. 030-15203
License No. 34-19008-01MD

As a result of the inspection conducted on December 18 and 20, 1990, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (1990) (Enforcement Policy) the following violation was identified:

License Condition No. 21 requires licensed material to be used in accordance with statements, representations, and procedures contained in certain referenced applications and letters, including the application dated August 15, 1984.

The application dated August 15, 1984 states in Attachment 2, Item (I) that all radiopharmaceuticals dispensed from the nuclear pharmacy shall bear a prescription number and the proper label.

Attachment 2, Item (J) of the referenced application requires that each dose container be labeled to include, among other information, the pharmaceutical form.

On November 23, 1990, 12 radiopharmaceutical doses which the licensee dispensed from the nuclear pharmacy did not have proper labels in that the incorrect pharmaceutical form was listed on the dose container label. Specifically the dose containers listed the pharmaceutical form as Tc-99m methylene diphosphonate (MDP) when the actual pharmaceutical form was Tc-99m diethylenetriamine penta-acetic acid (DTPA).

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

Pursuant to the provisions of 10 CFR 2.201, you are required to submit to this office within thirty days of the date of this Notice a written statement or explanation in reply, including for each violation: (1) the corrective steps that have been taken and the results achieved; (2) the corrective steps that will be taken to avoid further violations; and (3) the date when full compliance will be achieved. Consideration may be given to extending your response time for good cause shown.

1-15-91
Dated

William H. Schultz
William H. Schultz, Chief
Nuclear Materials Safety
Section 1