

APPENDIX
NOTICE OF VIOLATION

Syncor Corporation
Oklahoma City, Oklahoma

Docket No. 30-20964/91-01
License No. 35-23359-01MD

During an NRC inspection conducted on January 14-15, 1991, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990), the violations are listed below:

- A. License Condition 23 requires, in part, that licensed material be possessed and used in accordance with statements, representations, and procedures contained in an application dated January 20, 1984.
1. Item 10.C of the application specifies the procedure to be used for conducting dose calibrator constancy tests, including the requirement that for each source measured, the net activity versus the date will be plotted on semilog (graph) paper.

Contrary to the above, as of January 15, 1991, the licensee had not plotted the net activity versus the date for sources measured when conducting dose calibrator constancy tests.

This is a repeat violation.

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

2. Item B.2, Attachment 2, of the application specifies that (radiopharmaceutical) reagent kits will be redistributed as received from the manufacturer in the (original) "kit sleeve" and accompanied by the manufacturer's approved package insert.

Contrary to the above, during the period February 27, 1989, through January 15, 1991, the licensee had redistributed (radiopharmaceutical) reagent kits in other than the manufacturer's original packaging and without the manufacturer's approved package insert.

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

Pursuant to the provisions of 10 CFR 2.201, Syncor Corporation, is hereby required to submit to this office, within 30 days of the date of the letter transmitting this Notice, a written statement or explanation in reply, including for each violation: (1) the reason for the violation if admitted, (2) the corrective steps which have been taken and the results achieved, (3) the corrective steps which will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Where good cause is shown, consideration will be given to extending the response time.

Dated at Arlington, Texas,
this 4th day of February 1991