

NOTICE OF VIOLATION

Syncor Corporation
Ferndale, Michigan

License No. 21-17189-01MD

As a result of the inspection conducted on August 23-24, 1989 and October 24, 1989, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, (1989) (Enforcement Policy) the following violations were identified:

1. License Condition No. 20 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The referenced application dated January 5, 1988, states in Items 10.13 and 10.15 that labels attached to syringes and unit dose containers will contain information describing the pharmaceutical's chemical form.

Contrary to the above, on three separate occasions in 1987 and 1988 labels placed on pharmaceuticals and containers which were dispensed to client facilities did not contain correct information which described the pharmaceutical's chemical form. Specifically, on April 16, 1988, technetium-99m sodium pertechnetate was dispensed from the pharmacy that was labelled Pyrophosphate, on April 4, 1988, two unit doses of MDP bone doses were dispensed from the pharmacy labelled as Choletic and on June 22, 1987, a unit dose of MDP bone dose was dispensed from the pharmacy labelled as MUGA.

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

2. License Condition No. 20 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The referenced letter dated April 6, 1988, states that a sign is posted in the window of transport vehicles which states: "This Vehicle is Used to Transport Radioactive Drugs."

Contrary to the above, on July 20 and August 13, 1989, private vehicles used to deliver emergency doses to area hospitals did not display the required sign in the window of the vehicles.

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

3. License Condition No. 20 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced applications and letters.

The referenced application dated January 5, 1988, states in Item 10.8 that the emergency procedures found in Appendix I of "Guide for the Preparation of Applications for Nuclear Pharmacy Licenses" would be followed. Appendix I requires in part that when a minor spill occurs, licensees are to notify persons in the area that a spill has occurred; prevent the spread of contamination and clean the area using remote handling tongs.

Contrary to the above, on August 29, 1989, a minor spill of radioactive material (technetium-99m) occurred and persons in the area were not immediately notified of the spill. Furthermore, the licensee failed to prevent the spread of the contamination when an attempt was made to clean the contamination with a mop, thus spreading the contamination to other areas in the pharmacy.

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.

December 6, 1989
Dated

Bruce S. Mallett
Bruce S. Mallett, Ph.D., Chief
Nuclear Materials Safety Branch