

APPENDIX A

NOTICE OF VIOLATION

Syncor Corporation  
Pittsburgh, Pennsylvania 15201

Docket No. 030-15134  
License No. 37-18467-01MD

As a result of the inspection conducted on August 28 and 29, 1990, and in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy) (1990), the following violations were identified:

- A. Condition 23 of License No. 37-18467-01MD requires that the licensee conduct its programs in accordance with the statements, representations, and procedures contained in the application dated August 15, 1984, and letters dated January 9, 1985, January 9, 1986, September 19, 1986, December 16, 1986, January 26, 1987, March 12, 1987, February 27, 1988, April 13, 1988, and April 27, 1989.
1. Item 12 of application dated August 15, 1984, requires that individuals who work in or frequent restricted areas be instructed in the items specified in 10 CFR 19.12 at the time of initial employment and at least annually thereafter.

Contrary to the above, as of August 29, 1990, individuals who worked in or frequented restricted areas were not instructed in the items specified in 10 CFR 19.12 at least annually after initial employment. Specifically, the drivers and distribution personnel were not given annual refresher training as required.

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

2. Item 14, "Package Opening Procedures", of application dated August 15, 1984, requires, in part, that radiation levels at three feet from all packages containing radioactive material be measured and determined to be less than 10 millirem per hour, then the radiation levels at the surface of the package be measured and determined to be less than 200 millirem per hour, prior to opening the package and a wipe of the source container be made.

Contrary to the above, as of August 29, 1990, radiation levels at three feet from all packages containing radioactive material were not measured and determined to be less than 10 millirem per hour, before the radiation levels at the surface of the package were measured and a wipe of the source container was made. Specifically, all packages containing radioactive material including 2.7 curie technetium-99m generators, were wipe tested and a radiation level measurement of the surface of the outer package made before the radiation levels at three feet were measured.

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

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- B. 10 CFR 71.5(a) requires, in part, that each licensee who transports licensed material outside the confines of its plant comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation in 49 CFR Parts 170-189.

49 CFR 173.415 requires, for DOT Specification 7A Type A packaging, that each shipper of a Specification 7A package maintain on file for at least one year after the latest shipment, complete documentation of tests and an engineering evaluation or comparative data showing that the construction methods, packaging design, and materials of construction comply with that specification.

Contrary to the above, as of August 29, 1990, Type A containers were used for shipping radioactive material without maintaining on file complete documentation of tests and engineering evaluation or comparative data showing that the construction methods, packaging design, and materials of construction comply with that specification. Specifically, no results of tests and engineering evaluation or comparative data were maintained which addressed Type A containers packed with excess weight (i.e., additional unit dose containers placed into the containers than were originally tested).

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

- C. 10 CFR 20.401(b) requires, in part, that each licensee maintain records showing the results of disposals made under 10 CFR 20.302.

10 CFR 20.302 requires, in part, that the Commission approve procedures to dispose of licensed material in a manner not otherwise authorized in the regulations of this part. The Commission approved those procedures contained in Item 18 of the licensee's application, dated August 15, 1984.

Item 18 of application dated August 15, 1984 states, in part, that the licensee will dispose of radioactive material to the normal trash after holding the radioactive material for ten half-lives, surveying the waste to determine that background radiation levels are not exceeded, and recording the results.

Contrary to the above, on December 22, 1989, January 7, 1990, January 18, 1990, and May 2, 1990 the licensee did not maintain records showing the results of disposals made under 10 CFR 20.302. Specifically, the licensee disposed of radioactive material to the normal trash after holding the radioactive material for ten half-lives, and the records of the disposals were not maintained.

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

Pursuant to the provisions of 10 CFR 2.201, Syncor Corporation 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.