

NOTICE OF VIOLATION

The Cleveland Clinic Foundation
Cleveland, Ohio

License No. 34-00466-01

As a result of the inspection conducted on March 7 through April 20, 1990, 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. 10 CFR 35.33(c) requires the licensee to notify the referring physician and the appropriate NRC office in writing within 15 days if a diagnostic misadministration involved the use of byproduct material not intended for medical use, administration of a dosage five-fold different from the intended dosage, or administration of byproduct material such that the patient is likely to receive an organ dose greater than 2 rem or a whole body dose greater than 500 millirem.

Contrary to the above, as of April 4, 1990, the licensee did not notify the referring physician and the NRC office in writing within 15 days of a diagnostic misadministration that occurred on January 4, 1990. The misadministration involved the administration of a dosage five-fold greater from the intended dosage. Specifically, a patient received 90 microcuries of iodine-131 instead of the intended dosage of 15 microcuries of iodine-131.

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

2. License Condition No. 16 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in certain referenced documents. The referenced letter dated March 13, 1987, states in Part IV, "Misadministrations", that if a misadministration is suspected or confirmed the nuclear physician will be immediately informed. The letter states that the physician will ensure that the proper authorities including the radiation safety officer and the referring physician have been contacted.

Contrary to the above, when a misadministration was suspected by a technologist on January 4, 1990, the nuclear physician was not informed until April 4, 1990.

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


Notice of Violation

2

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.

Dated

5/22/90



Charles E. Norelius, Director
Division of Radiation Safety
and Safeguards