

NOTICE OF VIOLATION

Cleveland Clinic Foundation
Cleveland, Ohio

License No. 34-00466-01
Docket No. 030-02649

During an NRC inspection conducted on January 21, 1993, 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 (1992), the violations are listed below:

1. 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 10 CFR 35.11(b), shall require the supervised individual to follow the instructions of the supervising authorized user and follow the written radiation safety and quality management procedures established by the licensee.

10 CFR 35.32(a) requires, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. The quality management program must include, in part, written policies and procedures to meet the objective that each administration is in accordance with the written directive.

Item 3, of the licensee's quality management program entitled "Policies and Procedures for Diagnostic and Therapeutic Radiopharmaceutical Uses," requires the licensed user or designee to verify, before administering the byproduct material, that the specific details of the administration are in accordance with the written directive. The radiopharmaceutical, dosage, and route of administration will be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive.

Contrary to the above, on November 11, 1992, prior to administering byproduct material, the supervised individual (designee of the licensee) did not follow the quality management procedures established by the licensee. Specifically, the supervised individual did not confirm the dosage of the radiopharmaceutical prior to administration to verify agreement with the written directive.

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

2. 10 CFR 35.32(a) requires that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. The quality management program must include, in part, written policies and procedures to meet the objective that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

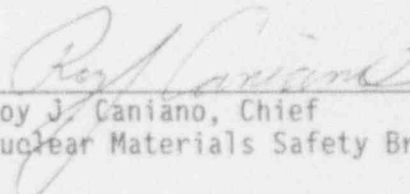
Contrary to the above, the licensee's quality management program does not include written policies and procedures for identifying, evaluating, and correcting unintended deviations from written directives.

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

Pursuant to the provisions of 10 CFR 2.201, Cleveland Clinic Foundation is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois, 60137, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

MAR 12 1993

Dated _____



Roy J. Caniano, Chief
Nuclear Materials Safety Branch