

NOTICE OF VIOLATION

Cleveland Clinic Foundation
Cleveland, Ohio

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

During an NRC inspection conducted on September 4, 1996, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and procedure for NRC Enforcement Actions," NUREG-1600, the violations are listed below:

1. Condition No. 39(B) of License No. 34-00466-01 states that the licensee shall conduct its program in accordance with statements, representations and procedures contained in letter and attachments dated May 12, 1992.

One of the attachments to the letter dated May 12, 1992 entitled Summary of Modifications to Renewal Application, Item 10 states: "We will adopt the model safety rules in Appendix I, Regulatory Guide 10.8, Revision 2." Appendix I states either after each procedure or before leaving the area, monitor your hands for contamination in a low-background area.

Contrary to the above, on August 27, 1996, a radiation safety technician failed to monitor his hands for contamination in a low-background area at the end of a iodine-131 therapy treatment or before leaving the area where the treatment was performed.

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

2. 10 CFR 20.1501 requires that each licensee make or cause to be made surveys that may be necessary for the licensee to comply with the regulations in Part 20 and that are reasonable under the circumstances to evaluate the extent of radiation levels, concentrations or quantities of radioactive materials, and the potential radiological hazards that could be present.

Pursuant to 10 CFR 20.1003, *survey* means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation.

Contrary to the above, on August 27, 1996, two nuclear medicine technologists did not make adequate surveys to assure compliance with 10 CFR 20.1201, which limits radiation exposure to occupational workers. Specifically, at the conclusion of an iodine-131 therapy treatment, two nuclear medicine technologists performed a survey of their hands and bottom of their shoes; however, they failed to detect the contamination on their laboratory coats and tops of their shoes.

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

3. 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the instructions of the supervising authorized user.

The instructions of the supervising authorized user, entitled "¹³¹I-NaI TREATMENT PROTOCOL," dated 1993, required, in part, that administration of liquid iodine-131 shall be only by way of a special straw provided for this purpose.

Contrary to the above, on August 27, 1996, a nuclear medicine technologist, an individual under the supervision of the licensee's authorized user, failed to follow the authorized user's instructions when she removed the rubber stopper from a vial of volatile iodine-131 and administered the dosage in a paper cup.

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

The NRC has concluded that information regarding the reasons for the violations, and the corrective actions taken and planned to correct the violations and prevent recurrence are already adequately addressed on the docket in Inspection Report No. 030-02649/96002 (DNMS) and a letter from Cleveland Clinic Foundation, dated September 26, 1996. However, you are required to respond to the provisions of 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, 801 Warrenville Road, Lisle, Illinois 60532-4351, within 30 days of the date of the letter transmitting this Notice of Violation.

Dated at Lisle, Illinois
this 1st day of November 1996