

NOTICE OF VIOLATION

Cleveland Clinic Foundation
Cleveland, Ohio

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

During an NRC inspection conducted on May 5-9, 1997 with continuing NRC review through May 21, 1997, a violation of NRC requirements associated with License No. 34-00466-01 was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," NUREG-1600, the violation is listed below:

Condition 39 of License No. 34-00466-01, Amendment 67, requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in a letter dated May 12, 1992.

Item 10, Section 16.5 of the referenced letter, entitled "Amendment Request to Radioactive Material Authorization," requires an Authorized User to limit total possession of requested radioisotopes to those types and quantities approved by the Radioisotope and Radiation Safety Committee (RRSC).

Contrary to the above, on numerous occasions between September 1996 and March 1997, Authorized Users exceeded total possession limits for various radioisotopes as set forth by the Radioactive Material Authorization form requested by the Authorized User and approved by the RRSC. For example, in September 1996, an Authorized User possessed 90 millicuries (3.33 GBq) of Hydrogen-3, which exceeded his inventory limit by 40 millicuries (1.48 GBq).

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

This is a repeat violation.

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, 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 (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. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. 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.

Because your response will be placed in the NRC Public Document Room (PDR), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be placed in the PDR without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

Dated at Lisle, Illinois
this 11th day of June 1997