

NOTICE OF VIOLATION

Antiviral Research Laboratory
Rockville, Maryland

Docket No. 030-32506
License No. 19-07538-06

During an NRC inspection conducted on January 22, 1997, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG 1600, the violations are listed below:

Condition 22 of License No. 19-07538-06 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in an application dated August 9, 1991.

1. Tab B of the application, contains a floorplan of the facilities where licensed material is used. This plan includes rooms 300-306, 308-315, 317-324, the BACTEC and radioactive waste storage room.

Contrary to the above, as of January 8, 1997, licensed material was used in rooms 2339 and 2341, rooms not included in the floor plan of the facilities.

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

2. Item 5.1, on page 9, of the application states that whole body exposures will be evaluated with film badges or TLD's on a monthly exchange basis. Doses to the extremities will be evaluated with TLD ring badges for users of phosphorus 32 who handle more than 10 millicuries in one month. These will also be exchanged monthly.

Contrary to the above, as of January 21, 1997, whole body and extremity exposure was not evaluated on a monthly exchange basis. Specifically, the licensee monitors TEDE and extremity dose with TLD badges that are exchanged quarterly.

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

Pursuant to the provisions of 10 CFR 2.201, the Division of Antiviral Drug Products, Antiviral Research Laboratory 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 I, 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

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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.