

NOTICE OF VIOLATION

Genzyme Transgenics Corporation
Worcester, Massachusetts

Docket No. 030-04605
License No. 20-01489-01

During an NRC inspection conducted on September 24, 1996, 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 No. 24 of License No. 20-01489-01 requires that licensed material be possessed and used in accordance with the statements, representations, and procedures contained in an application dated January 27, 1988 and a letter dated October 18, 1989.

- A. Item 3 submitted in the letter dated October 18, 1989 requires portable survey instruments to be calibrated at an interval not to exceed 6 months.

Contrary to the above, as of September 24, 1996, a review of the calibration records of five selected survey instruments, serial numbers 96154, 96516, 13967, 79520 and 57112, indicates that these survey meters were calibrated on September 26, 1995, and were next calibrated on June 27, 1996, an interval which exceeds 6 months.

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

- B. Item 10 in the application dated January 27, 1988 states: "We conduct annual training in radiation safety for principal investigators, users of radioactive material, shipping and receiving personnel, electricians, plumbers, and security."

Contrary to the above, as of September 27, 1996, three users of radioactive material did not receive training in 1996, annual training was not provided for one individual from 1993 to 1996, and one person did not receive training in 1995.

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

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Notice of Violation

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Pursuant to the provisions of 10 CFR 2.201, Genzyme Transgenics Corporation 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 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 AS, and provide the legal basis to support your request for withholding the information from the public.