

## NOTICE OF VIOLATION

Amicon, Incorporated  
Danvers, Massachusetts

Docket No. 030-19493  
License No. 20-19900-01

During an NRC inspection conducted on January 13, 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:

- A. 10 CFR 20.1101(c) requires a licensee to periodically (at least annually) to review the radiation protection program content and implementation.

Contrary to the above, the licensee did not adequately review the radiation protection program for content and implementation in 1994 and 1996. While reviews were performed in those years, the reviews were not adequate because they were essentially checklists and not actual evaluations of the radiation safety program.

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

- B. Condition 17 of License No. 20-19900-01 requires the licensee to conduct their program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures.

Item 2, entitled "Radiation Surveys," submitted with the letter dated June 24, 1993, states: "Surveys of the isotope labs are performed by the laboratory workers on a daily basis, on those days that work takes place, and once a month by the Radiation Safety Officer."

Contrary to the above, radiation surveys were not performed by the Radiation Safety Officer in February 1993, September 1995, and August 1996.

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

Pursuant to the provisions of 10 CFR 2.201, Amicon, Incorporated 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,

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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.