

MILLIPORE

February 26, 1997

United States Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington DC 20555

Reply to a Notice of Violation
Docket No. 030-19493
License No. 20-19900-01

Pursuant to the provisions of 10 CFR 2.201, Millipore Corporation, having acquired the assets of Amicon, Inc, is submitting this statement in response to Mr. Kinneman's January 29, 1997 letter and notice of violation.

A. Radiation protection program content and implementation review.

VIOLATION

It is the responsibility of the facility radiation safety officer to periodically review the content and implementation of the Radiation Protection Program. While it is desirable, when feasible, to have an independent audit of the program, the radiation safety officer must ensure that the quality of the audit is adequate to meet the requirements of 10 CFR 20.1101. The audits of 1994 and 1996 did not meet this criterion.

RESPONSE

1. The Radiation Safety Officer at Millipore's Bedford facility, Ms. Pamela Hubley, will be responsible for conducting annual, unannounced audits of the Danvers radiation protection facility. These audits will be comprehensive, and will detail the areas examined and observations made. The end result will be a report distributed to the management.
2. The audit program will commence within the three month period, May to July, 1997, and continue annually.
3. Full compliance will be achieved before July 31, 1997, by which time the first audit will have been conducted.

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B. Monthly Radiation Surveys conducted by the Radiation Safety Officer

VIOLATION

The facility's license specifically requires the Radiation Safety Officer to conduct the monthly surveys. When the officer or the assistant failed to conduct a timely survey on three occasions - February, 1993, September, 1995 and August, 1996, the facility violated the conditions of its license.

RESPONSE

1. The radiation safety officer conducted the January, 1997 monthly survey rests with in a timely manner.
2. Beginning with the February, 1997 survey, the radiation safety officer will schedule the survey to performed on, or the last work day before, the 25th of the month. The 26th and 27th will be reserved so that license conditions can be met should an emergency situation prevent a survey on the 25th. If the radiation safety officer is unable to personally conduct the survey, the survey may be delegated to the assistant radiation safety officer. However, the responsibility for ensuring that a proper survey is conducted remains with the radiation safety officer. This responsibility includes training, scheduling and follow-up inquiry.
3. Full compliance will be achieved on or before February 28, 1997, when the February survey will have been completed.

Millipore believes these procedure and policy changes will prevent further violations of its license. The helpful suggestions made by Mr. James Bondick during his inspection are appreciated.

Sincerely,



Robert W. Spillman
Director, Analytical R&D

CC: USNRC Regional Administrator, Region I

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