DCD/DCB (RIDS)

January 29, 1990

Docket No. 030-04972
License No. 22-00052-59MD
EA 89-231

Minnesota Mining and Manufacturing
Company (3M)
ATTN: Mr. Allen F. Jacobsen
Chairman and Chief
Executive Officer
3M Center 220-14W-04
St. Paul, MN 55144-1000

Gentlemen:

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORTS NO. 030-04951/89001, 030-04952/89001, 030-04972/89001, 030-04971/8901, AND 030-10825/89001)

This refers to a special safety inspection conducted during the period October 30 through November 3, 1989, to review actions taken by 3M in response to items identified during two NRC team inspections conducted on June 14 through July 28, 1988 and August 1-11, 1988, and actions taken by 3M in response to an NRC order dated February 18, 1988. The report documenting the inspection was sent to you by letter dated December 21, 1989. This also refers to 3M's December 22, 1989 letter in which you described defects you had identified in brachytherapy sources manufactured by 3M. The NRC concerns relative to the inspection findings, as well as other matters, were discussed during a telephone enforcement conference on November 30, 1989, between Mr. Stanley W. Thiele, Senior Vice President, Administrative Services, Mr. James W. Benson, Vice President, Medical Device Division, and other members of your staff, and Dr. Carl J. Paperiello, Deputy Regional Administrator, and other members of the NRC staff. A summary of the Enforcement Conference is contained in the inspection report.

Our evaluation of the inspection findings and of your letter dated December 22, 1989, has been completed and we have concluded that certain of your activities are in violation of NRC requirements, as described in the enclosed Notice of Violation (Notice). The inspection showed that, contrary to the requirements of 10 CFR 21.21(a), 3M failed to adopt Part 21 procedures to provide for evaluating deviations and informing the licensee or purchaser of the deviation and to assure that a 3M director or responsible officer is informed if a basic component supplied for such facility or activity contains a defect. This matter came to NRC's attention as a result of our evaluation of a failure of a

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3M 25 millicurie cesium-137 brachytherapy source in a Heyman applicator at the Yale-New Haven Hospital in March 1989. According to the hospital's Radiation Safety Officer, the source, which was brazed to a wire, became detached at the braze point. As a result, the detached source remained in a disposable applicator, was discarded in the ordinary hospital trash, and was subsequently recovered only after the trash was rejected at its destination. On September 27, 1989, 3M notified NRC that a similar cesium-137 source had separated from its wire at Mansfield General Hospital in Mansfield, Ohio.

NRC is concerned because 3M did not have specific Part 21 procedures for evaluating potential defects and notifying a director or responsible officer if a defect is determined to exist, and also because of 3M's apparent lack of action over the past few years after it became aware of problems with cesium-137 brachytherapy sources in Heyman applicators that are used by medical facilities. NRC had to intervene before 3M took effective steps to evaluate these problems and report an associated defect to NRC as required by 10 CFR 21.21(b).

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1989) (Enforcement Policy), the violation described in the enclosed Notice has been classified as a Severity Level III problem because it contributed to your delay in making a required notification to NRC under 10 CFR Part 21. Since the failure to make a timely notification does not appear to have been the result of a knowing and conscious act by a director or responsible official as defined in 10 CFR 21.3, a civil penalty is not being proposed. However, you should be aware that this matter is of serious regulatory concern. More significant enforcement action, including modification, suspension, or revocation of your license, is available to the NRC should related violations occur in the future.

During the enforcement conference, the NRC staff also expressed concern over 3M's failure to fully implement the comprehensive corrective actions that were described in 3M's July 18, 1988 response to an NRC Order to Show Cause dated February 18, 1988, and in 3M letters dated September 19, October 14, October 20, and December 2, 1988, and January 16, 1989, in response to the two NRC team inspections. In these responses, 3M committed, among other things, that Health Physics Services (HPS) would have the responsibility for auditing all radiological-related activities of manufacturing, distribution, quality assurance, product reliability, sales, technical service, product literature, product safety, and regulatory compliance. In addition, 3M stated it had created a Regulatory Affairs Product Reliability and Quality Assurance Organization which would ensure adherence to procedures and NRC regulatory requirements. However, as recently as November 30, 1989, this new Organization had conducted only one

audit and that audit was not in a radiological area. While HPS audits have been conducted of in-house radiation safety issues and documentation has been improved to assure corrective action is taken regarding audit findings, we are concerned that the HPS audit of manufacturing and distribution activities has been limited only to the Static Eliminator program.

During the enforcement conference, your staff emphasized that 3M did not commit to implement these actions by a specified date. In addition, 3M has delayed implementation of some phases of the audit program because of business decisions regarding the radioactive source manufacturing program.

We believe a delay of more than 16 months without implementing the entire audit program to which 3M committed is not reasonable, does not constitute an acceptable level of performance by 3M management, and is inconsistent with NRC expectations. Further, ongoing business decisions do not constitute justification for 3M's failure to promptly implement commitments.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response to the violation described in the Notice, and in your response to the concerns discussed above regarding 3M's failure to fully implement the comprehensive corrective actions that 3M previously described, you should describe the specific corrective actions that you plan to take or have taken. During the enforcement conference, 3M agreed that it would prepare and submit a response to the NRC Region III office no later than January 31, 1990, and would include a detailed description of 3M's audit program for all areas of licensed activity, a list of milestones when each component of the audit program will be implemented, and the dates when completed audit results will be available for NRC review. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the Commission's regulations, a copy of this letter, the enclosures, and your response to this letter will be placed in the NRC Public Document Room.

The responses directed by this letter and the accompanying Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

We will gladly discuss any questions you have concerning this inspection.

Sincerely,

Original signed by
A. Bert Davis

A. Bert Davis
Regional Administrator

Enclosures:
1. Inspection Reports
   No. 030-04952/89001;
   No. 030-04957/89001;
   No. 030-04971/89001;
   No. 030-04972/89001;
   No. 030-10825/89001
2. Notice of Violation

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