MAR 2 1 1988

The Honorable Paul S. Sarbanes
United States Senate
Washington, D.C. 20510

Dear Senator Sarbanes:

Thank you for your letter on behalf of Mr. Jon McGarity regarding the proposed regulations governing the certification of respirators.

The current regulations under which the Mine Health and Safety Administration and the National Institute for Occupational Safety and Health test and certify respirators (30 CFR Part 11) were originally promulgated in 1972. During the last several years, there has been a growing consensus among the respirator manufacturers and user community that these requirements need revision to reflect the technical advances in the field and the increased knowledge regarding environmental factors in the workplace. Some of the steps taken to develop the proposed rule are outlined in the enclosed preamble (52 FR 32402).

We are, of course, anxious to receive comments on both the technical and policy elements of this proposed rule. Toward that end, in October we announced two public hearings (52 FR 37639). The first took place in San Francisco on January 20, 1988, and the second was January 27-28, 1988, in Washington, D.C. Enclosed is a copy of the opening statement from those hearings which clarifies many of the misunderstandings of this regulation. We have also extended the comment period until March 28, 1988 (53 FR 5595).

We look forward to hearing from all parties concerned, and I assure you that all comments received will be placed into the record and will be carefully considered in any final rulemaking decision.

Sincerely yours,

J. Donald Millar, M.D.
Assistant Surgeon General
Director

Enclosure

cc:
NIOSH/W
NIOSH/Docket Office

CDC:NIOSH:LSparks
NIOSH #3257
Doc. 3195C

PAUL S. SARBANES
MARYLAND

PLEASE REPLY TO:
1518 G.H. FALLON FEDERAL BUILDING
31 HOPKINS PLAZA
BALTIMORE, MD 21201
(301) 962-4436

United States Senate

WASHINGTON, DC 20510

January 19, 1988

Mr. Larry Massanari
Regional Commissioner
Department of Health and Human Services
P.O. Box 8788
3535 Market Street
Philadelphia, Pennsylvania 19101

Dear Mr. Massanari:

Enclosed is correspondence that I recently received from Mr. Jon McGarity of 309 Songwood Court, Millersville, Maryland 21108 regarding the attached.

It would be appreciated if you would review this matter and provide me with a report so that I may be able to respond appropriately.

With best regards,

Sincerely,

Paul S. Sarbanes
United States Senator

PSS/bsf
Enclosure

December 18, 1987

Senator Paul S. Sarbanes
Dirksen Office Building - SD332
1st and C Streets N.W.
Washington, D.C. 20510

Dear Senator Sarbanes:

The National Institute for Occupational Health and Safety (NIOSH) currently certifies respirators for use in general industry, mining and construction. On August 27, 1987, NIOSH proposed (42 CFR 84, Federal Register) regulations which will have a disastrous impact on worker safety and on our industry.

The Industrial Safety Equipment Association, of which 3M Company of St. Paul, Minnesota is a part, feels strongly that this proposal must be withdrawn.

The proposal provides no prototype, nor specific requirements, so it is impossible for us to exercise our right to comment on it in a meaningful way. This denies us due process.

While our industry recognizes the value of regulation and, by and large, has little problem with the concept of workplace testing, the fact of the matter is that the technology is not available to conform to the proposed change. This is not the way to improve a process; it will, in fact, destroy a process which works but needs tuning.

Even though ninety percent of the respirators in use today are used for non-mining (industrial and construction) purposes, the proposal requires that we test all respirators under mining conditions, thereby ignoring the safety interest of the majority of workers who use respirators.

Finally, the proposed changes will cost our industry up to $700,000,000, which will threaten the very viability of the industry, as well as worker safety.

The management and employees of 3M Company trust that we can count on your support in this matter of critical interest to labor and industry. We urge you to immediately contact Health and Human Services Secretary, Dr. Otis Bowen, to request that the proposed ruling be withdrawn. Enclosed is a fact sheet which outlines the proposal, our objections and recommendations.

I look forward to hearing from you once you have contacted Secretary Bowen, as we are very anxious about the resolution of this problem.

Thank you for your assistance on this matter.

Sincerely,

Jon H. McGarity
309 Songwood Court
Millersville, MD 21108

ISEA FACT SHEET

(NIOSH proposal to change certification process for respirators)

I. Current Situation:

The National Institute for Occupational Safety and Health (NIOSH) currently certifies respirators for use in general industry, mining and construction.

II. Proposed Changes:

On August 27, 1987, NIOSH proposed (42 CFR part 84, Federal Register) to limit its certification activities to respirators used in mining, thereby requiring manufacturers of respirators used in general industry and construction to "self-certify" their products.

Manufacturers will be required to test their own respirators in the workplace or a simulated environment. However, the proposed "workplace" stipulation requires that all testing be conducted in mining operations.

All respirators currently in use will have to be recertified under the new process and manufacturers will be required to retest any respirators which are modified in the most minor ways.

III. Concerns about Proposed Changes:

(1) Testing in and for the Wrong Environment:

Ninety percent of respirators used in the United States are for non-mining use. By limiting respirator testing to mining, NIOSH is ignoring the safety and health needs of the vast majority of respirator users.

(2) Economic Impact:

The costs of developing new standards, recertification of existing respirators and workplace testing (with no proven protocols) would create an unbearable burden on manufacturers and end users. The net effect would be a major set-back to worker safety.

(3) Effects on Industries which Provide Respirator Protection for Workers:

It is likely that modifications required to make general industry respirators meet mine standards, as well as the increased costs of the end product, will adversely affect worker safety. Employers who have workers in marginal need areas may no longer provide respirators. Moreover, workers may not be willing to use respirators which are potentially too large, too unwieldy and uncomfortable.

(4) Requirement for Workplace Testing:

While the Industrial Safety Equipment Association (representing every major respirator manufacturer in the United States) is not in principal opposed to workplace testing, consensus standards and procedures must first be developed.

For example, it is presently impossible to test the broad array of different respirators in the workplace because the technology is not yet developed.

Even if the technology for workplace testing existed, there are not enough mines in the United States in which the tests can be performed without threatening the safety of workers.

(5) "Self-Certification" is a Misnomer:

Given the fact that NIOSH will review test results, reserve the right to retest at its discretion and continue to have the ultimate say, manufacturers will, in effect, not be certifying. Instead, they will be testing their products for NIOSH.

(6) Proposed Rule is Major Ruling and not a Minor Ruling:

Implementation of the proposed rule would cost manufacturers up to $700,000,000 annually, making the proposed rule a "major ruling" and not a "minor ruling" as portrayed by NIOSH. This would cause hardship on manufacturers and end users and be in conflict with Executive Order 12291.

(7) No Protocol Issued with Proposed Regulation:

While NIOSH has issued its proposed standards for certification, it has not released a protocol outlining the requirements, rules, details and procedures for the required workplace testing. This omission denies respirator manufacturers due process and, furthermore, makes it impossible for them to respond to the proposal in a meaningful way because it is not complete.

IV. Recommendations:

(1) The Proposed 42 CFR 84 must be withdrawn.

(2) If NIOSH is to no longer certify respirators for general industry and construction, resources must be committed to developing a consensus standard for all respirator certification for use in all industrial applications.

(3) This consensus standard must then be certified through a non-governmental third party.