DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEB 22 1988

84-252

The Honorable Harris W. Fawell House of Representatives Washington, D.C. 20515

Dear Mr. Fawell:

Thank you for your letter of February 5 to Secretary Bowen 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 extended our original comment period and announced two public hearings (52 FR 37639). The first took place in San Francisco on January 20, 1988, and the second was in Washington, D.C., on January 27-28, 1988.

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,

/s/ Robert E. Windom
Robert E. Windom, M.D.
Assistant Secretary for Health

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Enclosure

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HARRIS W. FAWELL

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Congress of the United States House of Representatives

Washington, DC 20515

February 5, 1988

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Honorable Otis Bowen
Secretary, Department of
Health and Human Services
200 Independence Avenue
Washington, DC 20201

Dear Mr. Secretary:

The National Institute for Occupational Safety and Health (NIOSH) has proposed regulations which many of my constituents say would impose heavy economic costs on general industry and the construction industry. I am writing to ask that you consider their objections.

On August 27, NIOSH proposed (42 CRF 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. Consequently, all respirators currently in use will have to be recertified under the new process and manufacturers will be required to retest respirators which are modified.

My constituents say that the proposed regulations will impose heavy economic costs on manufacturers. The costs of developing new standards, recertification of existing respirators, and workplace testing are not minimal. In fact, it is estimated that the proposed rule would cost manufacturers up to \$700 million.

Finally, they maintain that the proposed rule could actually jeopardize worker safety. The modifications required to make general industry respirators meet mine standards could 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 and designed for the mining industry.

Thank you for your attention to this matter. I look forward to your reply.

Very truly yours,

Harris W. Fawell, M.C. 318 House Office Building

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The Hon. Harris W. Fawell 115 W. 55th Street Suite 100 Clarendon Hills, IL 60514

Dear Congressman Fawell:

The National Institute for Occupational Safety and Health (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 Siebe North Inc. is a part, feels strongly that this proposal must be withdrawn.

The proposal provides no protocol, 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 90 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 Siebe North Inc. 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.

Thanks for your assistance on this matter.

Sincerely,

William J. Tweyer

William J. Toerpe

26W 430 Natalie Ct. Wheaton, IL 60188

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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 nonmining 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 setback 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 (Tepresenting every major respirator manufacturer in the United States) is not in principle 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) Discontinuation of NIOSH Testing:

Departing from current respirator certification practices, NIOSH will discontinue pre-certification testing of respirators and will only review test results submitted by manufacturers, validating those results.

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

Implementation of the proposed rule would cost manufacturers up to \$700,000,000 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) NIOSH should continue testing respirators as part of the certification process.
- (3) Workplace testing should not be instituted until technology is developed to make it reliable.