DEPARTMENT OF HEALTH AND HUMAN SERVICES

84-173

JAN 25 1988

The Honorable Cus Yatron House of Representatives Washington, D.C. 20515

Dear Mr. Yatron:

Thank you for your letter of December 23 on behalf of Mr. Don McCroskey and Mr. Richard Sustello regarding the proposed regulations governing the certification of respirators. Please excuse the delay in responding.

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 is scheduled for January 27-28, 1988, in Washington, D.G. 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,

Otis R. Bowen, M.D.

Otis R. Bowen, M.D. Secretary

Enclosure

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Page 2 - The Honorable Gus Yatron

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CDC Official File (Return to CDC, Atlanta)
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PHS Tracer No. T90704
CDC ID #D40906; NIOSH #3125; Doc 3465B
Prepared by Larry Sparks, CDC, FTS 236-3061, 12/29/87
Contact Karen Lindauer, CDC, FTS 236-3322
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GUS YATRON

REPLY IF ANY TO

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Congress of the United States

Nouse of Representatives Washington, DC 20515-3806

December 23, 1987

COMMITTEE ON FOREIGN AFFAIRS

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INTERNATIONAL ORGANIZATIONS
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AND CIVIL SERVICE

SUBCOMMITTEE ON HUMAN RESOURCES

SUBCOMMITTEE ON INVESTIGATIONS

The Honorable Otis R. Bowen Secretary Dept. of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Mr. Secretary:

I am appealing to you on behalf of Mr. Don McCroskey and Mr. Richard Sustello, General Manager and Product Development Manager, respectively, at Willson Safety Products, PO Box 622, Reading, Pennsylvania 19603.

Mr. McCroskey and Mr. Sustello are strongly opposed to proposed changes in the NIOSH's standards for certification of respirators used in general industry, mining and construction. As you know, these regulations require that respirators be tested in a mining environment. Since most respirators are used in non-mining environment, these regulations place a great burden on manufacturers and do not address the needs of workers who are employed in a non-mining environment. The enclosed correspondence should be self-explanatory. Any assistance or information you could provide in this matter would be deeply appreciated.

With kindest regards, I remain

Sincerely

GUS YATRON

Member of Congress

GY/erp

Enclosure

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P.O. Box 622 • Reading, PA 19603-0622 • 215/376-6161

December 16, 1987

Mr. Gus Yatron 2267 Rayburn House Office Building Washington, D.C. 20515

Dear Representative:

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 Willson Safety Products, a Division of WGM Safety Corp, Reading, Pa is a part, feel strongly that his 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 an estimate 90% 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 may cost our industry up to \$700,000,000 a year which will threaten the very viability of the industry as well as worker safety.

The management and employees of Willson Safety Products trust that we can count on your support in this matter of critical interest to (Berks County, Pennsylvania) 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,

V. D. McCroskey General Manager

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P.O. Box 622 • Reading, PA 19603-0622 • 215/376-6161

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Thanks for your assistance on this matter.

Sincerely,

Richard Sustello

Product Development Manager

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RESPIRATORY CERTIFICATION FACT SHEET

(NIOSH PROPOSAL TO CHANGE CERTIFICATION PROCESS FOR RESPIRATORS.)

I. <u>CURRENT SITUATION:</u>

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) limiting it's certification activities to respirators used in mining. This change, in effect, will require 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. Procedures for this "workplace testing" were not provided in 42 CFR 84.

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

III. CONCERNS ABOUT PROPOSED CHANGES:

(1) Testing in and for the wrong environment.

An estimated 90% 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, re-certification of existing respirators and workplace testing (with no proven protocols) would create and unbearable burden on manufacturers and end users. The net effect may 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 effect 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 Willson Safety Products is not in principal opposed to meaningful and consistent workplace testing, consensus standards and procedures must first be developed before we can endorse their use. 42 CFR does not provide adequate details to allow a proper review.

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 tests results, reserve the right to re-test 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 may cost manufacturers up to a hundreds of millions 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 it's 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, further more, 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 until it is complete and achievable.