DEPARTMENT OF HEALTH AND HUMAN SERVICES

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84-255

Mr. J. T. Eyan, Jr. Chairman Mine Safety Appliances Company Pittsburgh, Pennsylvania 35230

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Dear Mr. Dyan:

Thank you for your letter of January 6 to Senator Arlan Specter regarding the proposed regulations governing the certification of respirators.

The current regulations under which the Mine Bealth and Safety Administration and the National Institute for Occupational Safety and Health test and certify respirators (20 CFR Part II) 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 preamtle (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 FE 27639). The first took place in Can Francisco en January 20, 1988, and the second was in Washington, 9.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. William

Robert E. Windom, M.D. Assistant Secretary for Beauti

Enclosures

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Page 2 - Mr. J. T. Ryan, Jr.

cc:
The Honorable Arlen Specter
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H Official File
CDC Official File (Return to CDC, Atlanta)
CDC:JOMason;dc 02/25/88 FTS 236-3291 (M/02/25)
OS No. 8801280017; Tracer 91372; CDC ID D41254; Doc 3611B
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United States Senate

WASHINGTON, DC 20510

January 26, 1988

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

Dear Dr. Bowen:

I am writing on behalf of and at the request of Mr. J. T. Ryan, Chairman of the Board of the Mine Safety Appliances Company in Pittsburgh, Pennsylvania. The information contained herein was provided to me by Mr. Ryan.

According to Mr. Ryan, the National Institute for Occupational Safety and Health (NIOSH) is seeking to limit its certification activities to respirators used only in the mining industry. It is Mr. Ryan's sense that these changes are unnecessary and potentially detrimental to the respirator industry. Enclosed is a copy of Mr. Ryan's letter outlining his specific concerns.

I would appreciate your personal consideration of the points raised in the enclosed letter. Please respond directly to Mr. Ryan and forward a copy of your correspondence, in addition to a report on any action taken on this matter, to the attention of Justin Castillo of my staff.

Thank you for your attention to this matter.

Sincerely,

Arlen Specter

AS/jc Enclosure

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Senator Arlen Specter SH-303 Hart Senate Office Building Washington, DC 20510

Dear Senator Specter:

When you have a government agency and an important system that's working for both industry and labor, why would you change it?

That's the situation we face as the National Institute for Occupational Safety and Health (NIOSH), which currently certifies respirators for use in general industry, mining, and construction, now wants to limit its certification activities to respirators used in the mining industry only. This proposal (42 CFR 84) appeared in the Federal Register on August 27, 1987.

We believe the proposal must be withdrawn for the following reasons:

- 1. The government system of respirator certification (regardless of the application) does work, starting with the Bureau of Mines in 1919.
- By limiting certification to mining applications only, NIOSH is ignoring conditions where 90% of today's respirators are used.
- The estimated cost to respirator manufacturers of these proposed regulations is \$700,000,000. This could threaten the very viability of our industry, and/or prices of the product would increase dramatically, thereby setting off a negative economic spiral.
- While the Industrial Safety Equipment Association (representing every major respirator manufacturer in the United States) is not in principle opposed to workplace testing, consensus standards and procedures must first be developed. ISEA would support third-party testing under such consensus standards for all industrial applications.
- While NIOSH has issued its proposed standards for certification, it has not released a protocol oullining 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.

Senator Arlen Specter January 6, 1988 Page 2

6. Given the fact that NIOSH will review test 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.

MSA and all other respirator manufacturers in the ISEA 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. We understand that there's a consensus of support for the ISEA position from the industrial hygiene community, major respirator users, and labor unions. They, too, feel that today's system is working well and does not merit radical changes.

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,

J. T. Ryan, Jr.

Chairman of the Board

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 it's 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 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:

Ninety per-cent 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 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 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 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 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 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 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, 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 CRF 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Mr. J. T. Fyan, Jr. Chairman Mine Safety Appliances Company Pittsburgh, Pennsylvania 35230

Dear Mr. Ryan:

Thank you for your letter of January 6 to Senator Arlan Specter 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 (20 CFR Part II) 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 20402).

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 37630). The first took place in Can Prancisco en January 20, 1988, and the second was in Washington, N.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. Wheele

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Robert C. Windom. M.D. Assistant Decretary for Beauty

Enclosures

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cc:
The Honorable Arlen Specter

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H Official File (Return to CDC, Atlanta)
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