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The Honorable Joseph R. Biden, Jr.
United States Senate
Washington, D.C. 20510

Dear Senator Biden:

Thank you for your inquiry of March 18 on behalf of Mr. Brian McDonald regarding the proposed regulations governing the certification of respirators.

The current regulations under which the Mine Safety and Health 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).

The comment period for this regulation closed on March 28, 1988, after being open for a total of 7 months. During that time, 271 comments were received on both the technical and policy elements of this proposed rule. In addition, two public hearings were held; the first in San Francisco on January 20, 1988, and the second in Washington, D.C., on January 27-28, 1988. Enclosed is a copy of the opening statement from those hearings which clarifies many of the misunderstandings of the original proposed rule.

Over the next several months, we will review each and every comment received and will carefully consider them in any final rulemaking decision.

Sincerely yours,

James O. Mason
James O. Mason, M.D., Dr.P.H.
Assistant Surgeon General
Director

Enclosures

Page 2 - The Honorable Joseph R. Biden, Jr.

Fluoridation referred to

cc:
OD
NIOASH
~~NIOASH/W~~
FMO
CDCW
ES/PHS
ASL/OS
CLO/OS

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CDC:NIOASH:LSparks
PHS Tracer No. T93032; CDC ID #D42198; NIOASH #3361
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Please direct response to:

The Hon. Joseph R. Biden, Jr.
United States Senate
Washington, DC 20510

Attn: Jeff May

CDC ID: 100190
DATE: APR 16 1988
Correspondence Unit, OS
Ext. 5000

OS/PHS: 5000

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United States Senate

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Washington, D. C., March 18, 1988

Respectfully referred to

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The Hon. Joseph R. Biden, Jr.
United States Senate
Washington, DC 20510

Attn: Jeff May

CDC ID: D	42198
DATE:	APR 04 1988
Correspondence Unit, OD	
Ext. 3322	

Joseph R. Biden, Jr.

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McDONALD SAFETY EQUIPMENT INC.
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January 11, 1988

Senator Joseph R. Biden
SR 489 Russell Senate Office Building
Washington, DC 20510

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Dear Senator Biden,

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

The Safety Equipment Distributors Association, of which **Mc Donald Safety Equipment Inc. of Wilmington, DE** is a part, feels strongly that this proposal must be withdrawn.

The proposal provides no protocols, 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 & 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% of the respirators in use today are used for non-mining (industrial & 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.

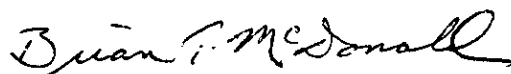
Finally, the proposed changes will cost our industry up to \$ 700,000,000 which will threaten the very viability of the industry as well as worker safety.

The management & employees of **Mc Donald Safety** trust that we can count on your support in this matter of critical interest to Delaware labor & industry. We urge you to immediately contact Health & 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.

Thank you in advance for your assistance on this matter and I look forward to hearing from you once you have contacted Sec. Bowen as we are very anxious about the resolution of this problem.

Sincerely,



Brian T. Mc Donald, President

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 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 ~~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, 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.