

3-16-88

84-215

The Honorable John H. Chafee
United States Senate
Washington, D.C. 20510

Dear Senator Chafee:

Thank you for your letter of February 8 on behalf of Mr. J. T. Ryan 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,

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

Enclosures

Page 2 - The Honorable John H. Chafee

cc:

OD

NIOSH

NIOSH/W

NIOSH/Docket Office

FMO

CDCW

ES/PHS

ASL/OS

CLO/OS

CDC:NIOSH:LSparks

PHS Tracer No. T92537; CDC ID #D41919; NIOSH #3297

Prepared by Larry Sparks, 3061

Contact Diane Porter, 3061

JOHN H. CHAFEE
RHODE ISLAND

CHAIRMAN, REPUBLICAN
CONFERENCE

FINANCE COMMITTEE

COMMITTEE ON ENVIRONMENT
AND PUBLIC WORKS

COMMITTEE ON BANKING
HOUSING, AND URBAN AFFAIRS

SPECIAL COMMITTEE
ON AGING

nl
United States Senate

WASHINGTON OFFICE:

WASHINGTON, DC 20510
(202) 224-2921

PROVIDENCE OFFICE:

301 JOHN O. PASTORE
FEDERAL BUILDING
KENNEDY PLAZA
PROVIDENCE, RI 02903
(401) 528-5294

TOLL FREE NUMBER
IN RHODE ISLAND
1-800-662-5188

ASH

February 8, 1988

Mr. Ronald F. Docksai
Assistant Secretary for Legislation
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Docksai:

Recently I received a letter, a copy of which is enclosed, from Mr. J. T. Ryan, III of Mine Safety Appliances Company, regarding new regulations proposed by the National Institute of Occupational Safety and Health.

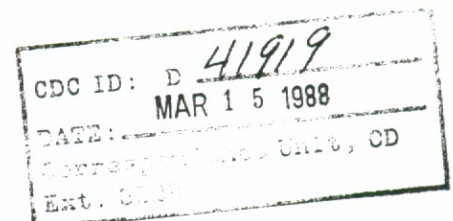
As Mr. Ryan's company has a large plant in my state that could be affected by these regulations, I am writing to request that you look into this matter. I would appreciate knowing your response to the concerns raised in Mr. Ryan's letter.

Thank you for looking into this matter.

Sincerely,

John H. Chafee
John H. Chafee
United States Senator

JHC/wkb
Enclosure





Mine Safety Appliances Company • P.O. Box 426 • Pittsburgh, PA 15230

Telephone: (412) 967-3000

December 30, 1987

Writers Direct Dial No.

Senator John Chaffee
SD-567 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Chaffee:

I appreciate the efforts that you and your staff have made over the last year in assisting us and our people in our Esmond, Rhode Island factory concerning the Department of the Army's strange procurement practices on military gas masks. This practice has become even stranger when, after having eliminated two producers, the DOA proceeded to pick the highest bidder of the two remaining companies that were allowed to make an offer. This must be the season for strange things coming out of Washington because we have run into another unfortunate and not logically constructed proposal by HHS which has a big impact on our company, our industry, and on our employees in Esmond, Rhode Island, who, in addition to military gas masks, are our company's source of manufacture for respirator facepieces.

For many decades the government has had a procedure for certifying respirators that are used in industry, mining, and construction to see that such respirators meet basic standards of protection for their users. For many years this was done by the United States Bureau of Mines; but with the passage of the Occupational Safety and Health Act, it moved to the National Institute of Occupational Safety and Health (NIOSH). While the original approval procedures used by the Bureau of Mines were naturally mining-oriented, for many years they had been used by general industry. The current system managed by NIOSH is enforced by the Occupational Safety and Health Administration (OSHA). The primary function of respirator certification has been to protect the workers of America by verifying that the products they use to protect their lives and health consistently meet a reasonable standard of performance. Additionally, this provides to the user companies who buy the respirators for their employees an impartial standard of performance that they can use in their employee protection and procurement decisions and a confidence that the products are consistently effective because long-term quality control procedures are involved. For the manufacturers, domestic and foreign, there is the benefit to know that they and their competition are on a level playing field with an assurance that all people in the market meet a minimum standard of performance and quality assurance and that there is not a bad quality product on the market from odd sources which could hurt people and, secondarily, give the entire industry a bad name.

The current system, like anything else, is not perfect; and as technology improves, there can be ways in which this certification procedure can be adjusted to provide to make it more effective. However, in recent years we had heard informally that elements within NIOSH wanted to get the agency out of the respirator certification business. While this would be very unfortunate, there could be alternate ways, acceptable to all concerned parties, in which their work could be done. But, recently NIOSH has proposed vast and radical changes in the certification process of respirators via their 42 CFR 84, as published in the Federal Register. The severe changes that they have proposed is a most unfortunate mistake that will hurt workers, users, and manufacturers in the safety equipment industry. In these proposals each manufacturer would have to do his own extensive amount of field testing of respirators for which there is not the technology available to provide consistency of test results and which would be devastatingly expensive without providing a meaningful improvement in the quality of the tests. Another defect in the NIOSH proposal is that it has not provided a detailed protocol of how such testing would be done, which makes it difficult for the companies involved to fully exercise their right to comment on the procedure in a meaningful way in advance. In any case, we can imagine that it would involve the extensive use of tests on randomly selected people where results could vary significantly by the type of people who are doing the test. As an example, when you put products on a marathon runner or a gymnast, you might get quite different results than if you put the same product on a person who is very heavy or someone who gets most of his exercise bending his elbow with cans of beer. Current certification testing is done on calibrated equipment that, while not fully simulating actual use, provides excellent consistency of results product-to-product, lot-to-lot, location-to-location.

A particularly strange aspect of these proposals is the fact that they require testing in a mining or simulated mining environment. It has been calculated that there are not enough mines in the United States to be used as testing sites for all the testing that is required under NIOSH's proposal. Furthermore and more importantly, the standards become completely oriented towards the mining environment when, in fact, 90% of the employees who use respirators are in an industrial or construction environment. This really is an indication of the illogic of this proposal.

Another negative factor in the proposal is that every petty product modification and adaption, even of a thoroughly insignificant detail, would require costly, extensive, and unnecessary full-blown field tests. A number of new requirements on respirators were put into the NIOSH proposal for which there is little or no demand among technical people or users in the field. The effect of this is to force respirators to be extremely large and bulky and thus very uncomfortable to the users, many of whom will find ways to get out of wearing them. These big bulky pieces of equipment would not provide significantly better protection to the wearer, only that he or she would not have to change the cartridge as often as in the present equipment. It is the general opinion in the field that this is a very poor trade-off; better to have the present lighter and more acceptable products and change cartridges every day instead of every second or third day.

It has been said that a lot of the mining orientation of these proposals is based on a literal reading of the original Congressional texts. This outlook forgets that over decades and decades it has been the intent of Congress that these respirator regulations be for a product used in all environments.

The result of these proposals would be a lessening in protection to the user because there is not a consistency and repeatability of test results, confusion to the buyers, discomfort to the wearers, greatly increased difficulties of companies to get their people to consistently wear bulky devices, and devastatingly extreme cost to the industry (estimated at \$700 million!), some of which would have to be passed on in increased prices and other of which can never be recovered because the use of respirators would probably decrease as a result of wearer resistance. As noted above, it is hard to fully comment on these proposals because they provide no protocol nor specific requirements which makes it impossible for us in the safety equipment industry to exercise our right to comment on it in a meaningful way. This denies us due process and is one of the reasons that we are appealing to you and your associates in Congress to intercede to have these proposals withdrawn.

In the activities made by our trade association--the Industrial Safety Equipment Association (ISEA)--on this issue, we have found that there is a strong consensus in the industrial safety and health community against these regulations. People involved in this consensus are part of it for different reasons, but there is general agreement that these proposals are a mistake. Many unions do not like it because it diminishes the protection that the workers have, whereby products are tested and approved by an independent government agency according to a consistent, reliable test procedure. They also don't want their people subject to unnecessarily uncomfortable products. Companies which use the product are concerned about the increased expense of a bulky product that has to be tested according to strange and elaborate procedures and about the difficulty in getting their people to wear the product. Industrial hygiene and safety and health professionals are concerned about this acceptability of respirators, about the fact that the bulkiness is not required by the needs of people that use them, and about the difficulty in carrying out their responsibilities if they cannot be assured of products that must pass a consistent, repeatable testing procedure. We in the safety equipment manufacturing industry are extremely concerned about this proposal which would cause us we estimate to spend together \$700 million to comply with the requirements that have no real basis and because we would have to design a product that the market does not want. Finally, many serious people in the government involved in safety and health do not agree with the NIOSH proposals either for a combination of all of the above reasons.

There is an alternative if NIOSH truly wants to get out of the respirator certification process. As in many other products, there can be a consensus standard developed over time by all involved parties including professionals, corporations, unions, and manufacturers to have an effective basis for certification of respirators. Then, respirators could be certified through a non-governmental third party to provide most of the protection presently given under NIOSH certification.

Mine Safety Appliances Company

The management and employees of MSA very much request your support in this matter of critical interest to labor and industry. Could you please contact Health and Human Services' Secretary Dr. Otis Bowen immediately and urge that the NIOSH proposal 42 CFR part 84 be withdrawn. For further details, please refer to the enclosed fact sheet put out by our trade association. On this matter there is complete unanimity on all producers of respirators that these proposals are completely misguided.

Members of our management, professionals from our trade association, and I would be glad to discuss this matter further with you, and we would appreciate hearing from you on this matter. Thank you very much for your help.

Sincerely yours,



J. T. Ryan
Executive Vice President

Enclosure

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 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.