DEPARTMENT OF HEALTH AND HUMAN SERVICES

84-257

MAR 4 1988

The Honorable Timothy E. Wirth
United States Senate
Washington, D.C. 20510-4702

Dear Senator Wirth:

Thank you for your letter of February 10 to Secretary Bowen on behalf of Mr. G. J. Galyath 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

Enclosures

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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
CC/W	LRubin	3/1/88						

cc:
OD
NIOSH
FMO
CDCW
ES/PHS
CCU/OS
ASL/OS
CLO/OS
H Official File
CDC Official File (Return to CDC, Atlanta)
CDC:JOMason;dc 02/23/88 FTS 236-3291 (M/02/23)
OS No. 8802190038; Tracer 91940; CDC ID D41532; Doc 3587B

TIMOTHY E. WIRTH
COLORADO

COMMITTEES:
ARMED SERVICES
BANKING
BUDGET
ENERGY AND
NATURAL RESOURCES

United States Senate

WASHINGTON, DC 20510-4702

February 10, 1988

Dr. Otis R. Bowen
Secretary
Hubert H. Humphrey Building
Room 615F
Department of Health and Human Services
Washington, D.C. 20201

Dear Dr. Bowen:

I am writing to enlist your assistance in responding to the concerns of fellow Coloradan, G.J. Galyath. The enclosed letter reflects his concern about changes in certifying respirators for use in general industry, mining and construction by the National Institute for Occupational Safety and Health. Any help you can offer in this matter will be greatly appreciated. Please direct any correspondence on this inquiry to my Washington office: 380 Russell Senate Office Building.

Thank you in advance for your cooperation in this matter.

Sincerely yours,

Tim Wirth

Timothy E. Wirth

TEW/ky

1129 PENNSYLVANIA STREET
DENVER, CO 80203
303/866-1900

1003 MAIN STREET
GRAND JUNCTION, CO 81501
303/245-8044

830 N. TEJON ST.
SUITE 105
COLORADO SPRINGS, CO 80903
303/634-5523

UNITED BANK BUILDING
8TH AND MAIN ST.
SUITE 410
PUEBLO, CO 81003
303/542-6987

Send to Otis

7524 South Trenton Court
Englewood, Colorado 80112

December 21, 1987

Dear Senator Wirth:

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 3M Company of St. Paul, Minnesota is a part, feels strongly that this 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 ninety 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 3M Company 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.

Thank you for your assistance on this matter.

Sincerely,

G. J. Galyath

G. J. Galyath

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 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, 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 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 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 (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 test results, reserve the right to retest 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 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) 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.