Docket

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

84-164

JAN 25 1988

The Honorable Bill Hefner
House of Representatives
Washington, D.C. 20515

Dear Mr. Hefner:

Thank you for your letter of December 22 on behalf of Mr. Lincoln C. Bailey 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.C. 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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## House of Representatives
## Washington, DC 20515

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December 22, 1987

The Honorable Otis Bowen
Dept. Health and Human Serv.
200 Independence Ave. SW
Washington, D.C. 20201

Dear Secretary Bowen:

I am in receipt of the enclosed letter from my constituent, Mr. Lincoln C. Bailey, of Scott Aviation regarding the proposal of the National Institute of Occupational Health and Safety to change the certification process for respirators.

I would appreciate Mr. Bailey's views being given every consideration. Also, any comments you might provide me on this matter will be appreciated.

With kindest regards, I am

Sincerely yours,

Bill Hefner

BILL HEFNER
Member of Congress

BH/md

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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,

Lincoln C. Bailey
Vice President
Sales & Marketing
Health/Safety Products

LCB:ck
Enc.

**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 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.