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OD, DSR, NIOSH



November 12, 1987

Director, Division of Safety Research  
NIOSH  
944 Chestnut Ridge Road  
Morgantown, W. Virginia 26505

Dear Sir:

NIOSH has proposed a new standard for respirator certification, 42 CFR Part 84. This standard, should it become accepted in its proposed form, would have a profound negative impact on both end users and the respirator industry. Attached is a summary of some of the problems which would occur if the proposal becomes law.

Under this proposal, few respirators currently available today could pass the certification test requirement of the proposed new standard. Given state-of-the-art carbon and filtration technologies, product revisions required to meet the proposed standard would make these products so onerous to wear (bulky, hot, heavy, hard to breathe through, and generally uncomfortable) that workers would most likely refuse to wear them (see attached artist's rendition).

Additional major problems in 42 CFR Part 84 include: (1) the workplace tests required for respirator certification may not be technically possible to conduct. Further, the cost associated with such workplace studies would add hundreds of thousands of dollars to development costs and end user costs for respirators; (2) protocol and details concerning much of the workplace testing requirements are not included in the proposed standard, making timely comment on technical and economic feasibility issues impossible; and (3) the workplace tests required for respirator certification must be conducted in mines, rather than in the general industrial workplace. This requirement is not only totally impractical, it avoids testing respirators in the industrial environment in which they are used.

The proposal as it currently exists fails to identify sufficiently the substance of the workplace testing and simulated workplace testing that will be required for certification.

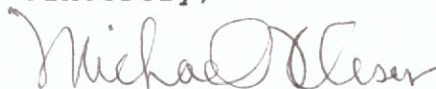
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Without further specificity regarding the details of such testing, it is impossible to evaluate and comment on the technical accuracy and feasibility of the proposed protocols. Mandatory undefined workplace testing, as NIOSH now proposes, certainly does not advance reliability and it is thus premature to require such testing before reliable protocols have been established. Accordingly, the proposed rule denies the opportunity for informed comments and criticism and the notice is therefore defective.

The University requests that NIOSH recall proposed Part 84 until it has developed protocols for workplace testing in sufficient detail to afford interested persons the opportunity to comment.

Sincerely,



Michael R. Ceser  
Environmental Health & Safety Officer

MRC/mh

Attachments(7)

cc: D. Roberts, Executive Director of Business Operations

KEY ISSUES ON NIOSH NOTICE OF PROPOSED  
RULEMAKING FOR TESTING AND CERTIFICATION  
OF RESPIRATORS FOR USE IN MINES AND MINING

The proposed new regulation for respirator certification (42 CFR Part 84, Federal Register, August 27, 1987) will have a disastrous impact on respirator users and their employers.

Worker safety will be compromised immediately by NIOSH's abandonment of its long-standing practice of certifying respirators for use in general industry and construction. In limiting its certification only to respirators for use in mines and mining, NIOSH purposely ignores the occupational safety and health needs of substantially more workers than it protects.

While ISEA and others have expressed concerns to NIOSH since many of the proposed changes were first drafted in 1982, most of these comments have been ignored. ISEA calls for a consensus standard activity to respond to the needs of all users of respiratory protection now and in the future.

Few, if any, of the respirators now on the market, which currently provide adequate protection, will meet the requirements of the proposed standard. Employers will be required to revise their respirator programs to accommodate those few respirators which satisfy the new requirements. These respirators will be, in many cases, larger, bulkier and more costly.

Contrary to NIOSH's opinion, these proposed rules will have significant economic impact on both the user community and respirator manufacturers.

The problems arising from the new proposed regulations can be divided into two categories: those dealing with general respirator requirements, and those dealing with the technical requirements for specific types of equipment.

#### I. General Requirements

- A. Workplace Testing of Respirators - While workplace testing of respirators is desirable, the proposal contains the following deficiencies:
  - 1. The proposed regulation contains the requirement that the performance of all respirators be tested in the workplace. The proposed rule states that the protocol and details for performing these field studies will be available at the time the final rule is promulgated. This represents a denial of due process of law by not allowing affected parties to comment on feasibility, cost and validity of requirements before they go into

effect. If NIOSH is going to proceed with a rulemaking hearing, then another hearing on the detailed requirements for field testing protocols should be held before the final rule is promulgated. For example, the proposal does not stipulate how many workplaces need to be included in the tests nor how many subjects in each workplace need be studied. A better alternative would be to recall the proposed rule until complete details are developed by NIOSH.

2. The proposed rule requires that during analysis of the workplace protection factor data, 95% of the test subjects must achieve a workplace protection factor in excess of the stated assigned protection factor with 95% confidence. There is too much variability in the test methods to require the use of confidence intervals. When the confidence interval is added to the prediction, no field test performed to date indicates any tested respirator can meet its assigned protection factor. For example, a half mask respirator with a minimum workplace protection factor (WPF) of 22 in the DuPont asbestos study would have a WPF of 6 using the NIOSH methods.
3. The proposed rule allows the use of simulated workplace testing in lieu of workplace testing if a good correlation can be established between the two types of tests. However, because the variables involved in workplace testing are so large, establishment of such correlations cannot be accomplished. To date, no lab tests have correlated to any workplace tests.
4. The proposed rule allows certification of respirators for use at protection factors greater than the assigned protection factor listed in the table if evidence is provided that the equipment performs at the higher protection level. Furthermore, an even higher confidence interval than the unachievable 95% confidence level for the base line protection factors must be met. NIOSH does not state what that confidence level should be. In effect the ultimate decision will be up to NIOSH, however, it is not stated what criteria must be met.
5. NIOSH is requiring all workplace testing be done with mines or mining operations as the workplace. Not enough mines exist to accommodate the number of tests required. NIOSH has stated unofficially that non-mining worksites may be used if correlations with mining worksites is established. Such correlations are not possible given the high variability intrinsic to these test methods. With all respirator manufacturers attempting to test several respirators per year with typical test periods a month, this would result

in test situations at virtually all the existing mines 100% of the time. Obviously mines would refuse to cooperate. In addition, while most types of respirators may at some time be used in mines, subjects wearing organic vapor or paint spray respirators, for example, would be hard to find.

6. Technology does not exist today to perform workplace testing against most hazardous substances found in the workplace. Analytical methods do not have sensitivity sufficient to make meaningful measurements of performance, especially with the respirators which have high assigned protection factors. Additionally, no methods exist for gas and vapor respirators.
7. The assigned protection factors, found on Page 32409, are very low for certain types of respirators such as continuous flow airline respirators, but are very high for positive pressure self-contained breathing apparatus. There is no justification given for NIOSH's assigned protection factors.

#### B. Modifications

All major modifications to a respirator will require repeat field testing of a respirator. A major modification is defined as one that "might appreciably affect weight, balance, strength or other qualities affecting respirator use or is not done according to accepted practices or cannot be done by elementary operations". This would be any change by definition. This will create another undue burden on the manufacturer and increased costs to the users.

#### C. General

42 CFR 84 eliminates general industry needs by certifying respirators for use in mines and mining. While OSHA and others may accept this certification for their use, general industry will not have respirators reflecting their needs.

## II. Technical Requirements

### A. Particulate Filter Efficiency

1. All respirator filters will be required to meet a loading filter efficiency test with both a liquid oil and solid aerosol 0.2-0.3 micron in diameter. Nearly all non-high efficiency respirators will fail the liquid oil requirements. Yet, workplaces having liquid oil contaminants are in the minority and are easily distinguished from workplaces having solid aerosol contaminants.

2. The oil mist loading test will eliminate all electrostatic filter media from respirators. This type of filter offers lower breathing resistance.
3. NIOSH has not responded to both the American National Standards Institute (ANSI) and ISEA requests that separate approvals be given for liquid and solid particles.

#### B. Chemical Cartridge Respirators

1. The proposed rule requires that gas and vapor respirators be equilibrated at 85% relative humidity, then tested at 85% relative humidity with a 50-minute service life requirement. No organic vapor chemical cartridge currently available in the U.S. today will meet this requirement. Organic vapor chemical cartridges will have to be made at least four times bigger to meet this requirement with today's technology. Respirator users have not expressed the need for longer service life for organic vapor cartridges.

#### C. Fit Test Panel

1. NIOSH is requiring the use of an anthropometric panel to size and assure fit of respirators. Manufacturers will be required to state the anthropometric size faces that their respirators will fit. No one to date has established a correlation between face length and face width and size of the respirator needed. Los Alamos National Labs, which developed the panel as a research tool, opposes the use of anthropometric panels in respirator certification.
2. The proposed rule implies to the user that since the respirator is certified to fit workers of a certain face size, and identified as such, that fit testing is not necessary.
3. The proposed rule requires 95% of the test subjects to exceed a fit factor of 50 for half masks and 100 for full facepiece respirators on a 25 person panel with a confidence level of 95%. Because of test variability most respirators will not meet this requirement. For example in one test on a 25 person panel a minimum fit factor of 120 was achieved on a half mask respirator. Using NIOSH's methods this would yield a fit factor of 31 and would not meet the requirements.

#### D. Tolerance Limits

1. NIOSH is using a three or six sample method of analyzing data to assure compliance with test requirements. Because of the normal variability in product

performance and test methods, many respirators will not meet the proposed requirements when compliance is based on such a small sample size. Thus many acceptable respirators in use today will be eliminated.

Recommendations:

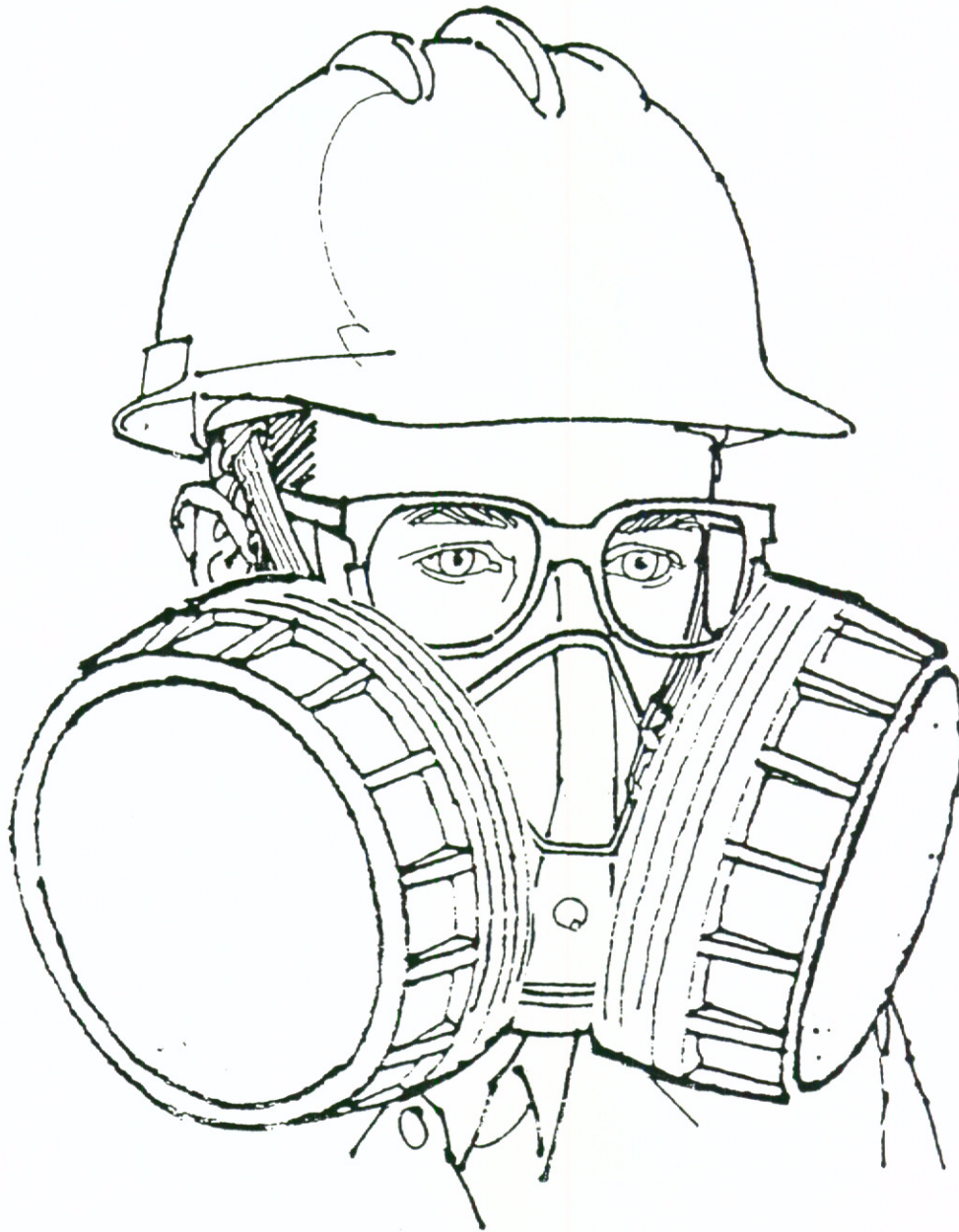
- A. 42 CFR 84 must not become final as proposed.
- B. NIOSH must clarify or recall its proposed rule before the scheduled hearing. Information in the proposed rule is far too incomplete or in some cases nonexistent to allow adoption.
- C. We urge all interested parties to submit detailed comments, due at this writing by December 28, 1987, on the proposed rule to:

Director, Division of Safety Research  
NIOSH, 944 Chestnut Ridge Road  
Morgantown, WV 26505

- D. Resources must be committed to develop a consensus standard for respirator certification for use in all industrial applications. Such a standard should be developed through an accredited ANSI Committee, and made available to OSHA and other government agencies.
- E. A non-governmental third-party certification program must be established to show compliance with respiratory protection standards developed through a consensus committee.

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GAS AND VAPOR RESPIRATOR  
AS REQUIRED BY NIOSH  
UNDER PROPOSED 42 CFR PART 84





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