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December 18, 1987
 9000-87-846

Mr. John Moran
 Director
 Division of Safety Research
 NIOSH
 944 Chestnut Ridge Road
 Morgantown, WV 26505

Dear Mr. Moran:

SUBJECT: PROPOSED NEW RESPIRATOR CERTIFICATION STANDARD, 42 CFR 84

GPU Nuclear Corporation supports the Industrial Safety Equipment Association, Incorporated (ISEA) in requesting the recall of 42 CFR 84 as proposed on August 27, 1987 (52 Fed. Reg. 32402). We fully endorse the position of the ISEA in this matter as found on the attached pages.

Sincerely yours,


 R. G. Ritthamel
 Manager, Industrial Safety & Health

RGR/LTB/KMB/jkg

Attachments: 1. ISEA Request for Recall of Proposed 42 CFR 84
 2. ISEA Summary of Key Issues of Proposed 42 CFR 84

cc: Mr. F. H. Grice
 Mr. A. W. Mills
 Mr. R. D. Holmes
 Writer's File

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FOR YOUR INFORMATION
FROM **ISEA**

WICKENS, KOCHES & CALE

84-053

WASHINGTON SQUARE

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September 21, 1987

Federal Express

Mr. John Moran
Director, Division of Safety Research
National Institute for Occupational
Safety and Health
944 Chestnut Ridge Road
Morgantown, West Virginia 26505

Re: Request for Recall of
Proposed 42 C.F.R. Part 84

Dear Mr. Moran:

On behalf of the members of the Respiratory Protection Group of the Industrial Safety Equipment Association, Inc. ("ISEA")^{*} we hereby request the recall of 42 C.F.R. Part 84 as proposed on August 27, 1987 (52 Fed. Reg. 32402) for the following reasons:

* The members of ISEA's Respiratory Protection Group are:

Airolife Safety Inc.
American Optical Corporation
Biosystems, Inc.
E. D. Bullard Company
Glendale Protective Technologies, Inc.
Mine Safety Appliances Company
Minnesota Mining and Manufacturing Co., Inc. (3M)
Moldex-Metric, Inc.
National Draeger, Inc.
Parmelee Industries
Pro-Tech Respirators, Inc.
Racal Airstream
Scott Aviation
Sellstrom Manufacturing Company
Siebe North, Inc.
Survivair - U.S. Divers Company
WGM/ Willson Safety Products

Under the Administrative Procedure Act, notice of a proposed rule must include "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. §553(b)(3)(1982). This requirement exists to assure that interested parties are afforded the opportunity to offer informed criticism or comments on agency proposals. See, Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1, 48 (D.C. Cir. 1976). In the instant proposal NIOSH has failed to give the detailed notice required by the APA, thereby denying an opportunity for informed comment and full participation by interested parties in the rulemaking process.

As set forth at 42 C.F.R. §84.31 through §84.34, the proposed rule requires workplace or simulated workplace testing prior to certification. The preamble to the proposed rule states that NIOSH will provide applicants detailed model protocols to perform these tests upon request. The preamble further states that NIOSH "has begun to develop model protocols for performing such tests in a proven and reliable manner."

NIOSH notes that these protocols when and if developed would be too voluminous to be included in the Federal Register notice. The preamble states NIOSH's intention, however, to make the protocols available at the time of final rulemaking. NIOSH thereafter solicits comments on these unidentified model tests that will supposedly "assure reliability and reproducibility of mandatory workplace and simulated workplace test results."

The foregoing proposal for workplace testing protocols is insufficient and should be recalled for further development. 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. Without further specificity regarding the details of such testing, it is impossible for ISEA, or NIOSH for that matter, to evaluate and comment on the technical accuracy and feasibility of the proposed protocols.

While ISEA and its members generally support workplace testing, such testing can only assure reliability of the equipment when reliability of the test method itself has been established. 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

Mr. John Moran
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been established. Accordingly, the proposed rule denies the opportunity for informed comment and criticism and the notice is therefore defective.

ISEA thus 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,


Paul A. Koches

PAK:mlr

cc: J. Donald Millar

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:

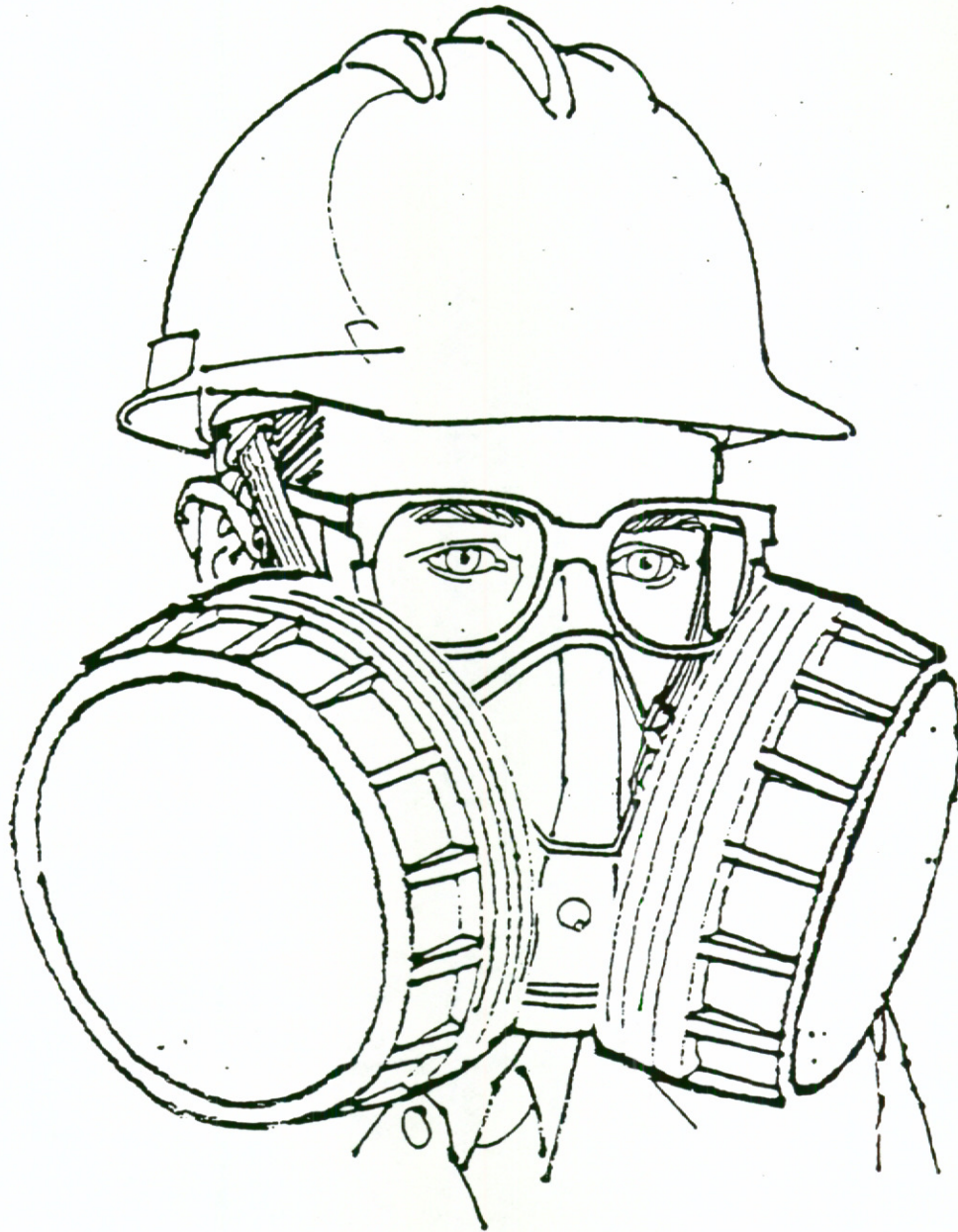
- A. 42 CFR 84 must not become final as proposed.
- B. NIOSH must clarify or recall its proposed rule before the scheduled hearing. Information in the proposed rule is far too incomplete or in some cases nonexistent to allow adoption.
- C. We urge all interested parties to submit detailed comments, due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

* * * * *

84-053
GAS AND VAPOR RESPIRATOR
AS REQUIRED BY NIOSH
UNDER PROPOSED 42 CFR PART 84



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

