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84-077

Pro-Tech Respirators, Inc.

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December 28, 1987

NIOSH Docket Office
Mail Stop E 23
1600 Clifton Road N.E.
Atlanta, GA 30333

Dear Sir or Madame:

I wish to participate in the public hearing meeting in Washington D.C., January 27 & 28, 1988, regarding CFR 42 Part 84 and would like to have ten minutes to speak on this topic.

I am in complete support of the ISEA comments on CFR 42 Part 84, which are enclosed.

I look forward to hearing from you.

Yours truly,

William F. Moon
President
Pro-Tech Respirators, Inc.

Enclosures

taq

cc: ISEA

Introduction

On August 27, 1987, NIOSH published proposed new respirator certification regulations (42 CFR Part 84) to replace the existing regulations presently contained in 30 CFR Part 11. 52 Fed. Reg. 32402 et seq. Thereafter, on October 8, 1987, NIOSH extended the comment period on its proposal to December 28, 1987 and announced "informal public meetings: to be held in January, 1988 with respect to the proposal. 52 Fed. Reg. 37639-37640. This document sets forth the position of Industrial Safety Equipment Association (ISEA), a respirator manufacturers association, with respect to the proposed new regulations.

Procedural Defects

Before turning to a point-by-point discussion of the proposed respirator certification regulations, ISEA feels compelled to renew its request that the proposed regulations be withdrawn completely because of procedural defects. See letters dated September 8, 1987 and November 2, 1987 from 3M Associate Counsel Nelson E. Schmidt to John Moran and Nelson Leidel, respectively and letter dated September 21, 1987 from ISEA Counsel Paul A. Koches to John Moran. The most important of these defects relates to the imposition of workplace test requirements, and specific protocols for performing those tests, without publishing the proposed protocols for review and public comment.[1]/

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[1]/ A related problem arises from NIOSH's proposal of provisions which are often exceedingly vague (e.g., proposed § 84.32(a)(2)) (Footnote continued on following page)

Specifically, NIOSH itself acknowledges that workplace testing is "[t]he most significant of the new requirements," and it indicates that is in the process of developing specific protocols which will "establish the criteria for the conduct of the tests." 52 Fed. Reg. at 32402. However, NIOSH has not published those protocols for review and comment, and it apparently has no intention of doing so because it states that the protocols would be "too voluminous to include in the Federal Register" and will be made available "at the time of final rulemaking." 52 Fed. Reg. at 32403.

In essence, then, NIOSH is proposing substantive requirements regarding the nature of workplace testing without even identifying those requirements, much less subjecting them to the public scrutiny and comment necessary for informed decision-making. This failure obviously runs afoul of the Administrative Procedure Act, which

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(Footnote continued from preceding page)

> or without an explanation of the reasons for the proposal. For example, the requirement that a sample of only three or six filter tests be utilized creates a significant problem for respirator manufacturers (see discussion below), but there is no indication why NIOSH believed that a limitation on the number of tests was advisable. Only if NIOSH identifies the concerns that underlie its proposal can the public address those concerns in any meaningful way. See, e.g., Connecticut Light and Power Co. v. Nuclear Regulatory Comm'n, 673 F.2d 525, 530 (D.C. Cir. 1982) ("If the notice of proposed rule-making fails to provide an accurate picture of the reasoning that has led the agency to the proposed rule, interested parties will not be able to comment meaningfully upon the agency's proposals. As a result, the agency may operate with a one-sided or mistaken picture of the issues at stake in a rule-making.").

mandates that notice of a proposed rule 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). The purpose of this notice requirement is to assure that interested parties are afforded an opportunity to offer informed comment and analysis (e.g., Ethyl Corp. v. Environmental Protection Agency, 541 F.2d 1, 48 (D.C. Cir. 1976)), and agencies must be especially cognizant of that purpose when proposing, or basing proposals on, technical data or analysis that is quintessentially amenable to expert analysis and evaluation. See Lloyd Noland Hospital & Clinic v. Heckler, 762 F.2d 1561, 1565 (11th Cir. 1985). Indeed, as the D.C. Circuit observed in Connecticut Light and Power Co. v. Nuclear Regulatory Comm'n, supra, 673 F.2d at 530-531:

> In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules. To allow an agency to play hunt the peanut with technical information , hiding or disguising the information that it employs, its to condone a practice in which the agency treats what should be a genuine interchange as mere bureaucratic sport. An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary (footnote omitted).

In sum, it is clear that any final NIOSH rule based on the current proposal will be procedurally defective and hence will not be able to withstand judicial review. In these circumstances, the responsible and wiser course obviously is to withdraw the instant proposal and defer rulemaking until NIOSH is in a position to publish a full and

proper proposal which will provide ISEA and other interested parties with a meaningful opportunity to participate in the rulemaking. ISEA urges NIOSH to follow this course.

Subpart A - General Provisions

84.1 Purpose

NIOSH is proposing to revise the regulations to test and certify respirators for use in mines and mining only. While the Mine Safety and Health Act of 1977 requires NIOSH to approve and certify respirators for mines and mining, the Act does not prevent NIOSH from approving and certifying respirators for non-mining use. In fact, NIOSH has in the past addressed the needs of non-mining general industry for certified respirators. More than 90% of the NIOSH approved respirators in use today are used in non-mining applications. Indeed, other regulatory agencies such as EPA, OSHA and NRC require NIOSH certified respirators for non-mining use. In many instances the respirator needs of the general industry user conflict with the respirator needs of the miner. (For example, a SCBA with harness designed to meet the needs of a fire fighter in mines may not meet the needs of the nuclear industry where decontamination is a major factor, since the fireproof design would most likely entail using a somewhat porous material that would trap radioactive material.) NIOSH should expand the scope of its respirator certification program to include the vast majority of respirator users in general industry.

84.2 Certified Respirators

(a) NIOSH is proposing to issue certifications based solely on a

review of manufacturer's test data. This constitutes a drastic departure from the current certification scheme where NIOSH tests and verifies that the respiratory equipment submitted for approval meets all certification requirements prior to issuing the certification. We believe NIOSH should continue to run all the certification tests on all equipment prior to issuing any approval. NIOSH testing ensures that all certified equipment has met the same performance requirements under the same testing conditions and lends more credibility and consistency to the program. In addition, if NIOSH regularly performs testing of products prior to certification, they will be in a better position to fulfill their role as a reference laboratory for correlation purposes.

(b) Expiration Of Manufacturers Certificates And Recertification

(1) NIOSH states the current certifications will expire five years from the effective date of the final rule. There are currently thousands of NIOSH/MSHA certified respirators which would require recertification under the proposed revision. As a consequence, five years time would not be sufficient for manufacturers to make the necessary changes to their respirators and for NIOSH to issue certifications. However, the users of these devices would have their respirator programs interrupted because of the unavailability of approved respirators in the interim. We therefore propose that a minimum of ten years be allowed to recertify current respiratory products.

(4) Under the new proposal, certifications granted after the effective date of these new regulations will remain in effect for the time period specified in the subsequent revision of the performance requirement applicable to that type or class of respirator. These proposed changes in the status of respirator certifications, however, will result in confusion for the end user and impose unnecessary costs to the manufacturer, which will ultimately be passed on to the respirator user.

NIOSH must carefully weigh the impact of such changes to future certification requirements before enacting them. This is especially important for respirator types that have a long useful life, such as SCBA. Purchasing this equipment represents a large capital investment by the employer and making such equipment obsolete for minor improvements is a disservice to the end user. NIOSH should consider grandfathering certifications for such equipment until their useful life is over, as was done in the past.

84.3 Definitions

The "major modification" definition is overly broad and unclear. It appears that NIOSH's intent, based on the explanation in section 84.60 of the preamble, is that only "major" modifications need resubmission. The proposed definition for major modifications, however, includes virtually any modification. Thus, by this definition, all changes would have to be submitted for approval. However, in the preamble to section 84.60, this does not appear to be

NIOSH's intent. Therefore, it is recommended that the definition be revised to read: "Major modification" is any modification that affects the performance of the respirator.

The definition for "respirator" should be modified by removing the restrictive reference to mines and mining as the only applicable work sites. (See comments on 84.1.)

Similarly, the definition for "simulated workplace" must be expanded to include work situations other than mines or mining worksites. Also, "reasonably representative" of mines or mining work sites needs to be clarified as to which parameters should be included in constituting a reasonable representation. (See comments on 84.1.)

"Workplace" should be expanded to any work site, and not be limited to "mine or mining work site" exclusively. (See comments on 84.1.)

Subpart B - Application Procedure

84.11 Required contents of an application to NIOSH for certification

(e) NIOSH is proposing to require the applicant to submit "informational" materials for approval. NIOSH does not define informational materials, so it is difficult to comment accurately on the scope and impact of this requirement. Clearly, however, advertising and sales literature should not be included as informational materials. ISEA submits that the best way to resolve this issue is to simply delete "informational" from the proposal.

(g) NIOSH is proposing to require a complete parts list, including all components or parts which may be replaced during the useful life of the respirator, with each application for certification. NIOSH has recently taken steps to reduce the paperwork burden on manufacturers via a letter to all respirator manufacturers, dated September 15, 1987. This reduced paperwork policy requires parts lists and drawings only for components listed on the approval plate. The requirement contained in this proposal is a complete and unwarranted reversal of that policy and should be abandoned in favor of the September 15, 1987 policy.

(i) NIOSH states that additional fees will be charged to cover any verification testing performed by NIOSH. Per earlier comments under section 84.2(a), we feel that NIOSH should be performing all required tests prior to issuing a certification. Accordingly, an appropriate fee schedule should be established.

(j) NIOSH is proposing to add a requirement for the manufacturer to comply with requirements in 45 CFR part 46, Subpart A, Basic HHS Policy for Protection of Human Research Subjects, during any testing involving human subjects required by the proposed regulations. It is difficult to comment on this requirement because NIOSH has offered no explanation for including the requirement or specifying which tests the requirement applies to. Presumably compliance would be necessary for workplace testing, faceseal leakage testing and man tests of SCBA's.

45 CFR part 46, Subpart A is a regulation covering research performed or funded by HHS. The HHS approval procedure is extremely burdensome and costly. The procedure could delay testing for months and would cost hundreds of thousands of dollars a year to implement and maintain. For example, the procedure requires that an Institutional Review Board (IRB) be set up to govern the subject testing. The IRB reports directly to both the Institution and the Secretary. The IRB's function and procedure is governed by written guidelines and procedures that must be pre-approved by the Secretary. The IRB must consist of members not having a conflict of interest with the research being conducted. This policy is normally applied to universities where volunteers from other departments can be used to make up the Board. However, a manufacturer would need to hire outside consultants for every position.

It is neither appropriate nor cost effective for NIOSH to require each manufacturer to go through the steps necessary to achieve HHS

approval for testing human subjects. It is also nonsensical for NIOSH to require testing that HHS may later rule is unsafe. A much more rational approach is for NIOSH to submit the proposal for those test requirements involving human subjects to HHS for approval. This is appropriate since the testing performed in each instance is nearly identical. For instance, a worker in a field test is typically outfitted with belt mounted personal sampling pumps, weighing less than two pounds each. One length of tubing runs from the respirator to a sampling pump while another length of tubing connects a sampler on their lapel to a second sampling pump. Anyone participating in a fit test is exposed to low amounts of non-toxic aerosols, while performing the same one-minute exercises. Likewise, subjects participating in evaluations of SCBA will perform standardized exercises.

If HHS decides specific precautions are needed for the testing, NIOSH can incorporate them directly into the certification requirements.

Subpart C - Quality Assurance

84.20 Quality Assurance

(a) NIOSH states that the applicant, as part of his QA program, must "inspect or test, or both, the critical characteristics identified in the appropriate subparts of this part". It is difficult to comment on this requirement because NIOSH has not defined the "critical characteristics" to which it is referring or which subpart is applicable. For example, if NIOSH intends that the applicant conduct workplace testing or faceseal leakage testing on each lot of respirators, then this would impose an impossible burden on the applicant. NIOSH must identify "critical characteristics" before meaningful comments can be generated.

(b) NIOSH states that applicants shall calibrate instruments used for inspection and testing of critical characteristics. "Critical characteristics" must be defined, however, before meaningful comments can be made.

(d) NIOSH is requiring applicants report to NIOSH any knowledge of a product distributed with critical characteristics not in accordance with certification specifications. "Critical characteristics" must be defined before meaningful comments can be made.

(e) NIOSH states in this section that it shall be permitted to conduct in-plant audits and inspections if they have reason to believe a certified respirator is in non-conformance with the

requirements of the part. We believe NIOSH should conduct periodic plant audits but with advance notice whether they have reason to believe the manufacturer is distributing non-conforming respirators or not. Periodic plant audits should be performed to assure compliance with good manufacturing practices.

(f) This section states applicants shall make certified products available for audit, upon request by NIOSH but not more than once a year except for cause, at no cost. It is difficult to provide meaningful comments on this section since NIOSH has not stated how many respirators will be needed for audit purposes. Providing products to NIOSH at no cost for compliance auditing could impose a significant financial burden on some manufacturers since several devices sell for more than $1000 each.

84.21 Discovery of defect or failure of compliance by manufacturer; notice requirements

This section requires manufacturers to notify NIOSH, and if so directed by NIOSH, dealers, distributors or purchasers of respirators, anytime the manufacturer discovers a respirator fails to comply with the quality assurance requirements of this part. We believe that it should not be necessary to notify NIOSH if defects are found in a production lot which has not been put into distribution, or if the lot is sorted and defective units removed before the lot is distributed. Production of occasional non-conforming material is normal to any manufacturing process. The

purpose of implementing quality control plans is to assure the material is not released for sale and distribution. We suggest that the intent of this paragraph and a related requirement in 84.22(b) for estimating number of defective units produced, be revised to state, "any respirator produced and distributed, which are no longer in the direct possession or control of the manufacturer..."

84.23 Notification by the manufacturer to affected persons

(b) (1) We suggest that the requirement for notification to purchasers of respirators be worded as follow: "By certified mail to purchasers of the respirator and to subsequent transferees, where known to the manufacturer".

84.25 Determination by NIOSH that a respirator fails to comply or has a defect

(c) There is an apparent error in section (c). It seems that section should read, "...NIOSH shall direct the manufacturer to furnish the notification to the persons specified in paragraph 84.21(c)" instead of 84.21(b).

Subpart D - Respirator Testing by Applicant

84.30 Laboratory testing by applicant and interim certification

(a) The second sentence should be modified to read: "In addition... performs as required...". The proposed word "expected" conotes a subjective standard rather than referencing a published performance requirement.

(b)(2) This section states the applicant shall submit a written test report which shall include, among other things, a detailed description of the test procedures employed in producing the test results. This section should be revised to allow references to standard test methods where they exist in view of detailed descriptions of test procedures. Otherwise an unnecessary and costly paperwork burden is placed on manufacturers.

(d) This section states that NIOSH can require as a condition of certification, additional tests reasonably necessary to evaluate the respirator, and that NIOSH must notify the applicant in writing of these requirements, and "generally" the reasons for the requirement. If NIOSH is imposing additional requirements, we believe they must state specifically, not "generally", the reasons for the added requirements.

(e) This paragraph states NIOSH will review the laboratory test report to determine if the respirator:

1) Meets the requirements

2) Performs as expected

3) Is free from defects or characteristics that may make it unsafe for its anticipated use.

2) "Performs as expected," should be deleted. This is a meaningless requirement since "expected" is a subjective term that is open to interpretation.

Similarly, the word "may" should be removed from number 3, "Is free from defects...that may make it unsafe for its anticipated use."

(f) This requirement states NIOSH must notify the applicant within 90 days of "acceptance" of the test report, whether the report provides evidence the respirator meets all the laboratory test requirements. The word "acceptance" should be replaced with "receipt". Receipt conveys that NIOSH is bound to process the applicant's paperwork and issue findings within a 90-day period, whereas "acceptance" implies NIOSH can have an undetermined amount of time after receiving the report before they decide to accept it, and then another 90 days to review the report and issue findings.

(f)(1) This section states NIOSH will issue an interim certification upon the applicant's demonstration of compliance with laboratory requirements, prior to commencement of field testing. We disagree with the requirement for inclusion of field testing as a component of certification as proposed by NIOSH, and believe final certification should be issued if the laboratory requirements are satisfied. See

comments below on field testing, section 84.31.

84.31 Guidelines for Workplace or Simulated Workplace Testing and

84.32 Workplace or Simulated Workplace Testing by Applicant; Certification of Minimum Performance Level

We disagree with NIOSH's addition of workplace testing to their proposed scheme for respirator certification. While workplace testing is a valuable tool for respirator research, it is too variable, costly and, for most applications infeasible to be a prerequisite for certification and the basis for assigning minimum performance levels to categories of equipment.

The proposed regulation contains the requirement that the performance of all respirators be tested in the workplace. The Preamble to 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. It is submitted that this represents a denial of due process by not allowing affected parties the opportunity to comment on feasibility, cost and validity of specified requirements before they go into effect. If NIOSH is going to proceed with rulemaking, then another rulemaking on the detailed requirements for proven and reliable field testing protocols should be held before the final rule is promulgated. For example, the proposal doesn't stipulate how many workplaces need to be included in the tests nor how many subjects in each workplace need be studied.

We are very skeptical that such a protocol can be formulated at this time. Furthermore, developing such a protocol, for what NIOSH termed is the "most significant of the new requirements", available at the conclusion of the rulemaking process, makes a mockery out of the entire rulemaking proceeding.

First, NIOSH is requiring all workplace testing be done in mines or mining operations. Not enough operational mines exist in the U.S. 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. Furthermore, with all respirator manufacturers attempting to test several respirators per year and considering a typical test takes a month to perform, testing would be in progress 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.

Secondly, workplace test results are unreliable in predicting respiratory performance. The inherent variability of the data makes it unusable for certification and does not assure reliability of the respirator to the user. Furthermore, analytical methods with very high sensitivity must be used in order to make meaningful measurements. For the few methods that do exist, necessary handling of the samples in the workplace greatly increases the possibility of contamination of the samples.

Technology does not exist today to perform workplace testing of respirators against most hazardous substances found in the workplace. Analytical methods do not have sensitivity sufficient to make meaningful measurements of performance, especially with those respirators having high assigned protection factors (APF). Additionally, no test methods exist for field testing gas and vapor respirators.

Yet, in spite of these inherent variables, NIOSH is coupling the requirement for field testing to very stringent performance criteria, i.e., the fifth percentile must exceed the APF for the category of equipment within the constraints of conservative statistical parameters.

For example, with respirators such as pressure demand SCBA or airlines with anticipated protection factors in the 1000 - 10,000 range, it is necessary to have contaminant concentrations that are much higher than the practical limit of analytical detection - analytical chemists have a rule of thumb that says at least 10,000 - 100,000 times higher. Finding workplaces with such consistently high contaminant concentrations, and sufficient numbers of workers in these high concentrations whose exposures are of a duration sufficient to collect valid samples over a reasonable period of time, would be impossible. It is highly unlikely that such workplaces exist anywhere, let alone in mines.

Third, and last, workplace studies are extremely costly. NIOSH

released a draft of a workplace field test protocol for peer review in August of 1987. The purpose of the Research Protocol was to verify the assigned protection factors for half and full facepiece negative pressure respirators. In order to make any meaningful cost estimates, however, a test protocol is needed. Because no proven reliable protocol exists, the respirator manufacturers were forced to use the draft research protocol developed by NIOSH as a basis for the cost estimate.

The protocol states that 126 data points will be required for each substance tested in each of the industries studied. NIOSH states that 3-6 substances for each type of respirator will be required. For the cost estimate, the industry selected a conservative number of three substances. For example, for a dust respirator, 3 different type dusts will be tested: for an organic vapor respirator 3 different organic vapors for an air line respirator 3 different substances; etc. The protocol also stated that different facilities in numerous industries would be studied. For this cost estimate, the industry conservatively chose to not factor in the need to evaluate different facilities or industries.

Experience in the industry has shown that to obtain 126 data points it has been necessary to collect samples from 200 tests in the workplace. Approximately 75 of the data points will be discarded after or during analysis because the workplace concentrations of the contaminant were too high or too low for valid analysis. In addition, some tests will be invalidated in the field due to pump failure, sample or sample line disconnections, etc.

Using industry experience and assumptions based on the NIOSH protocol, the following estimates were made:

ASSUMPTIONS FOR DETERMINING COSTS FOR WORKPLACE TESTING

Testing Costs

126 good samples per substance per industry are required. To obtain this, one needs 200 "good" tests in the field. This does not include those samples rejected in the field because of pump failure, respirator removal, etc.

	People weeks
35 "good" tests	5
200 "good" tests	30 (or 1,200 people hours)

Non-Testing Costs

Scouting "good site"	3
Preparing equipment for shipping	1
Cleaning equipment	1
Preparing samples	1
Tabulating results	4
Writing reports	4
Administration	3
	17 people weeks non-testing or (680 people hours)

Total: 1,880 people hours/200 "good" tests or 9.4 people hour/test or 14.92 people hours per usable data point

Other Direct Costs

$2.50/sample for collection media, 800 needed	$ 2,000
$30/sample analytical costs, 600 needed	18,000
$1,000/people week travel costs, 33 needed	33,000
Total:	$53,000 or $265 per test or $421 per usable data point

Cost of Respirators - additional direct cost

Indirect Costs

Reusable equipment	$80,000

Grand Total = 1,800 people hours + $53,000 + indirect costs per substance to get 126 usable data points

The overall cost estimate to do an in-field evaluation of respirator performance against one substance is $53,000 and 0.9 person years of effort. Based on this, the industry estimate for the cost of performing the proposed workplace testing would exceed $700,000,000 for currently approved respirators. Thus, the cost greatly exceeds $100 million and, on this basis, clearly constitutes a major rule. NIOSH's failure to conduct a regulatory impact analysis is a violation of Executive Order 12291. Accordingly, the proposed rule should be recalled and a regulatory impact analysis be conducted.

Further, the tremendous expense of field testing will place a severe burden on the user community, since the costs will ultimately be borne by the user.

Even with these very conservative assumptions, it is estimated that a manufacturer with a comprehensive product line would encounter a need to conduct over 1000 such field evaluations, an astronomically large testing burden. This adds up to direct costs of over 53 million dollars and over 1000 person years of effort for that manufacturer. This cost will, of course, ultimately be passed along to the consumer and will result in fewer models of respirators available to the user.

In addition, the general guidelines proposed by NIOSH in section 84.31 and 84.32 are impossible to comment upon without further explanation by NIOSH. For example, 84.31(c) requires that workplace or simulated workplace testing be done by experts qualified by training and experience. NIOSH has not stated what these qualifications are. There are currently only a few people in the

U.S. who have conducted any field tests and nearly all of those people are unavailable to general industry. In addition, some experts believe that many of the field tests have not been conducted in a manner yielding meaningful results.

Finally, NIOSH states in 84.31(b) that workplace evaluations of respirator performance shall be made in workplaces and in work conditions that are reasonably representative of the places and conditions in which it is anticipated the respirator will be used. It is impossible to estimate the number of workplace evaluations required per respirator because NIOSH has not specified the conditions one needs to consider in order to determine if the workplace or simulated workplace is representative of where the respirator will be used. There are thousands of conditions and environments in which respirators are used.

84.32 Workplace or simulated workplace testing by applicant; certification of minimum performance level

(a) The assigned protection factors (52 Fed. Reg. 32409) are very low for certain types of respirators such as continuous flow airline and low efficiency respirators (see discussion under 84.232 (j) regarding low efficiency respirators), but are very high for positive pressure SCBA. There is no justification given for NIOSH's assigned protection factors and thus it is once again impossible to comment without knowing NIOSH's reasoning behind the proposed numbers. However, we would recommend the assigned protection factors listed in

the proposed ANSI Z88.2 standard be adopted. Some rationale has been established for those numbers.

(a)(1) Change the work "expected" to "required by this part". Expected is a subjective response. Delete "may" so it reads: "which make it...".

(a)(2) This section is far too vague to comment on. For example, for which observations are methods to be provided,which results are to be recorded, which variables measured, which subjective responses measured, which biases measured? This section provides the commenter with no basis to form comments.

(b) This section is also too vague. It is impossible to comment on. For example, how many workplaces need measuring, how is one to determine which workplace is a representative of another, which conditions must be measured?

(b)(1) This section is too vague to comment on . How is it determined whether a person is properly fitted, and by what fit test method.

(b)(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, for a half mask respirator with a 5th percentile minimum workplace protection factor

(WPF) of 22 as determined in the DuPont asbestos study would have a WPF of 6 using the NIOSH methods.

(d) Change "acceptance" to "receipt".

84.33 Workplace or simulated workplace testing by applicant; certification of high performance level

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 and if confidence levels even higher than the unachievable 95% confidence level for the baseline protection factors is met. NIOSH does not state, however, what that confidence level would be. In effect, the ultimate decision will be up to NIOSH but they will not let the respirator manufacturers know what criteria will be used in advance of performing the test. In this instance, NIOSH is giving the appearance of providing alternatives. In reality, demonstrating performance to levels higher than required for baseline certification with this type of highly variable testing, is virtually inconceivable. A more viable alternative would be for OSHA to allow use at higher levels based on individual cases where employers can demonstrate higher levels of protection in their workplace to OSHA's satisfaction.

84.34 Availability of respirator test results and protocols

NIOSH states they will make available for public review, all laboratory and workplace test results and test protocols. ISEA submits this type of information should not be made available for public review if it contains trade secrets and/or confidential or financial information.

In addition part of the data collected in a workplace test is the equivalent to employee exposure monitoring data. Many companies consider this information to be confidential and would be very reluctant to participate in a study where that data was collected and made public.

Subpart E - NIOSH Certification Label

84.40 Required contents of a certification label

(a) (3) The requirement for placing "the lot number or other appropriate designation of date of manufacture" on the approval label is unnecessary and unworkable. This information is already required in section 84.41(b) to be "placed on each respirator, major respirator component and respirator container". Most certification labels are printed on the respirator or component package, inserted into the carton containing the respirator as a booklet or placed in the operating and maintenance manuals for the device. Often as many as 25 approval labels can accompany a particular respirator facepiece or component. The expense to change these booklets daily would be economically prohibitive and is unnecessary since this information is already on the packaging and on the respirator.

NIOSH should develop and require content specific warnings and cautions for approval labels.

(a)(9) Marking the fully charged and discharged weight permanently and legibly on each SCBA is not a feasible requirement. It is not possible to meaningfully comment on this paragraph since NIOSH has not stated why they have included this requirement. However, as stated this requirement would be virtually impossible to comply with. Respirators are approved for use with many accessories or options. Each time an accessory or option is added or removed, weight changes occur. Some can be very significant, such as switching from a steel

to an aluminum cylinder. In addition, the components themselves vary a great deal in weight from one to another. For example, one steel cylinder might differ in weight by 2 pounds from another of the same type.

84.41 General label and marking requirements

(b) NIOSH is requiring that each respirator, major respirator component and respirator container be distinctly labeled to show the name of the manufacturer, respirator or component designation and lot number, serial number or date of manufacture. It is very difficult to comment on this paragraph since NIOSH has not defined what a major component is. Some components of respirators such as valves and gaskets will have their performance adversely affected by the marking requirements, making such a requirement totally infeasible. The manufacturer should be responsible for identifying all components which are to be traceable in the quality assurance program.

Subpart F - Maintenance, Informational and Instructional Materials

84.50 Operation and maintenance manuals

(a) Manuals are not necessarily the optimum vehicle to convey the information necessary for proper use of a respirator. Some types of respirators, such as disposable respirators, do not require maintenance and have operating instructions that are brief enough to be placed on the packaging.

In addition, many disposable respirators are multiple-packed in a single box. Providing instructions for each is not necessary since the user has access to the box. In this instance providing instructions with each respirator is wasteful and unnecessary. Wording should be changed to read "operation and maintenance instructions shall be provided with each respirator container". Likewise, for subsequent sections in this part, sections (1), (2) and (b), the word "manual" should be replaced by the word "instructions" for the reasons stated above.

Subpart G - Modification of Certified Respirators

84.60 Major modification of certified respirators

Sections (a) and (b) under this part states that major modifications to respirators shall be submitted to NIOSH for approval and, that the respirators shall meet all the performance standards. A major modification is defined in section 84.3 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. Furthermore, if this requirement is interpreted literally, every time the slightest change was made to a respirator, changing the metal in a screw, for example, the manufacturer would be required to re-perform astronomically costly field evaluations. Beyond this, it is impossible to comment meaningfully on the requirements in these sections without making certain assumptions. NIOSH must state which performance tests an applicant must run if the modification affects only one component or attribute of a respirator. For example, if the applicant modifies the exhalation valve of a respirator, what would be the purpose of re-testing the respirator filters or cartridges? Or if a sorbent in a chemical cartridge is changed, why would the facefit or exhalation valve need re-testing, or if the elastomer in the facepiece of an SCBA is changed, why would the service life or flows need re-testing?

Section (c) of this part does not state what NIOSH will do if the modification meets the requirements and is approved. Will a new

approval be issued? Will the old approval be modified? It is impossible to comment without knowing NIOSH's intention.

Subpart H - Withdrawal of Certification

84.70 Withdrawal of certification for cause

Paragraph (g) of this part states that failure of a manufacturer to consistently produce a respirator that is reliable and free from defects or characteristics which may make it unsafe for its anticipated use constitutes cause for withdrawal of certification. Producing defective respirators is of no consequence to anyone but the manufacturer if they are not distributed. Accordingly, section (g) should be reworded as follows: "Failure of a manufacturer to consistently release for distribution respirators that are reliable and free from defects or characteristics which make it unsafe for its anticipated use".

Paragraph (h) states that a determination by NIOSH that the tests upon which they have based their decision to issue a certification do not provide assurance of protection to the user, is cause for withdrawal for certification. Paragraph (h) should be deleted. It is difficult to comment here because NIOSH has provided no insight into their intent in the preamble for such a requirement. If NIOSH means that the tests contained in this regulation may likely in the foreseeable future prove to have no validity or are not meaningful, then the whole regulation should be recalled and stayed until such time as valid and meaningful test requirements can be proposed. If in the future such information becomes available, new rulemaking can be initiated.

Subpart I - Appeals

84.80 Appeal procedure

This section sets up an appeals procedure, the outcome of which is not binding on the Director of NIOSH. This must be changed or in effect, no meaningful appeals procedure exists.

The Director of NIOSH must be bound by the Administrative Law Judge's ruling to revise, reverse, or affirm the original NIOSH determination. The wording should be changed by dropping the last sentence and adding "The decision of the administrative law judge shall constitute final agency action subject to review under the Administrative Procedures Act".

In addition, there does not appear to be a time limit between a manufacturer's appeal and the actual hearing before an administrative law judge. A reasonable time period such as 30 or 60 days should be included. The status of the product is unclear during that period of time.

84.90 Fees

Pursuant to the comments on Section 84.2, NIOSH should compute costs of testing and certifying respirators based upon the actual cost to conduct such tests and publish a fee schedule. For tests with insufficient data upon which to calculate a fee, NIOSH should charge

a flat or hourly rate based on the actual technical and support staff time plus the cost of any disposable test items. The fee schedule and hourly or flat rate charge should be updated annually based on a published index such as the Consumer Price Index and noticed in the Federal Register.

NIOSH's failure to provide an estimate of these costs constitutes a denial of an opportunity for interested parties to comment thereon and is in violation of the Administrative Procedures Act.

Subpart O - Technical Definitions

84.200 Definitions as used in this part

"dBA" The specific type of sound level meter used must be specified in this definition as different sound level meters have different response characteristics.

"Face Seal Leakage" Two methods for calculating facial leakage have commonly been used, the so called average or integration and the peak valve methods. NIOSH should specify which method is acceptable. If the peak valve method is acceptable, NIOSH should also list an acceptable frequency response of the measuring system.

"IDLH" The definition used should coincide with that proposed by the ANSI Z88.2 Subcommittee, namely "any atmosphere that poses an immediate hazard to life or poses immediate irreversible debilitating effects on health".

"Particulate Respirators" Change this definition to read"...respirator which removes solid and/or liquid particulates...". See our comments under 84.270 for an explanation.

"Loose fitting facepiece", "Tight fitting facepiece". Delete "gas" from gas-tight. Facepieces are designed to provide a contaminant-tight seal, not necessarily a gas-tight seal.

Subpart P - Classification

84.210 Classification of Certified respirators

Paragraph (b)(2) and the table contained in paragraph (c) should be amended by deleting continuous flow air-line respirators as a separate category since they are a form of a positive pressure air-line respirator. NIOSH states no reason for this treatment of continuous flow air-line respirators and therefore no meaningful comments can be submitted.

Thus, the table in paragraph (c) should be as follows:

Air-Line Respirators

Positive Pressure Air-Line
- Pressure Demand
- Constant Flow

Negative Pressure Air-Line

Hose masks and abrasive blasting respirators should also be included here based on the criteria contained in 30 CFR Part 11.

84.211 Combination respirators

Provisions for combination escape air-line respirators with an air-purifying mode should be included since NIOSH has allowed approvals of this type under the current standard. An air-line respirator, used in an air-purifying mode only for escape should have to meet a specified resistance requirement.

Subpart Q - General Constructions and Performance Requirements

84.220 General construction requirements

Section (e) states all respirators incorporating eyepieces or windows shall have an impact and penetration resistant lens which meets the requirements of ANSI Z87.1 - 1979. There is no provision in ANSI Z87.1 - 1979 to test lenses of respirator facepieces or helmets. Testing for eyeglasses in the ANSI standard specifies a fixture for holding the eyeglasses in place during the test. There is no such provision for eyepieces or windows in respirator facepieces or helmets. A specific test method should be specified by NIOSH to permit this testing.

In addition, we feel users should have the option of wearing safety spectacles under facepieces or helmet type respirators. Accordingly, this Section should be revised to state "All respirators shall permit wearing of safety spectacles which meet the requirements of ANSI Z87.1 - 1979 without adversely affecting the performance of the respirator or the respirators shall have an impact and penetration resistant lens or faceshield which meets the performance requirements of ANSI Z87.1 - 1979 in accordance with the test methods develped by NIOSH".

Section (h) states that respirators shall be constructed to minimize fogging of eyepieces, spectacles and windows. A performance based test should be specified to determine if resistance fogging is acceptable.

Section (l) states respirators shall be resistant to corrosion and deterioration from chemical physical agents to which they are likely to be exposed in the workplace. This requirement is so vague and subject to interpretation, comments as to feasibility of compliance are impossible. NIOSH must either replace this statement with a performance based requirement and test method or delete this paragraph altogether.

84.223 Body harnesses

Paragraph (c) of this Section states that body harnesses for self contained breathing apparatus shall not melt when exposed to temperatures of 400°F for 30 minutes. The attribute this test method evaluates is only of value for SCBA used in fire fighting. The type of harness meeting this heat resistance requirement is not suitable for many industry uses such as the nuclear industry where decontamination of this type of harness is not possible. Accordingly, that Section should be revised to state "Body harnesses for self-contained breathing apparatus certified for fire fighting shall not...".

In addition, "Shall not melt" should be replaced with "shall remain functional".

84.224 Respirator containers

(b) This paragraph states that containers may provide for storage of more than one respirator if such containers prevent contamination of respirators remaining in the container as other respirators are removed, and if such containers prevent damage to respirators during transit. This paragraph, as written, is too vague to allow manufacturers an opportunity to interpret and comply with the intent of the requirement. NIOSH should restate this requirement in performance based language, or delete it entirely.

(c) This paragraph states gas and vapor air-purifying respirators, as well as self-contained breathing apparatus, shall be packaged in containers to permit rapid removal. The need for this requirement is obvious for those respirators stored for emergency entry or escape. However, this requirement should not apply to <u>all</u> gas and vapor air-purifying respirators since the vast majority of them are destined and clearly marked for routine use. NIOSH should revise this requirement to apply only to emergency entry or escape respirators.

(d) This paragraph states that containers for self-contained breathing apparatus will be inspected, examined and tested. Again, without a test method or at least a performance based requirement, interpretation of and compliance with this requirement is impossible. NIOSH must either clearly state what is being required or delete the statement entirely.

84.225 Head harnesses

(a) This paragraph states the head harnesses of tight fitting facepieces shall be designed and constructed to provide adequate tension during use and an even distribution of pressure over the entire area in contact with the face. This requirement is superfluous and should be deleted since this characteristic is tested in other areas such as the face seal leakage requirements.

(b) This paragraph states that mouthpiece/noseclamp respirators shall be equipped with adjustable and replaceable harnesses designed and constructed to hold the mouthpiece in place. This requirement should be deleted. Mouthpiece respirators do not have or need adjustable or replaceable harnesses. The neck strap is not intended to hold the mouthpiece in place.

(c) This paragraph states that facepiece head harnesses must be adjustable. This implies the user must adjust the head harnesses. Disposable respirators have been produced with elastic type bands that are self-adjusting. This requirement is design and not performance based and therefore should be deleted. In addition, respirators with tight fitting facepieces that are not sufficiently "adjusting" to fit many sizes of faces and heads will not be capable of passing the face seal leakage test, Subpart R.

84.226 Inhalation and exhalation valves

(c)(2) This sentence is unnecessary since the subsequent Section, 84.227(b), contains a specific performance requirement for acceptable leakage of exhalation valves. Leakage for inhalation valves is not critical since the consequence is just backflow of clean air into air-purifying elements or air-lines supplying clean air to the wearer. It is impossible for manufacturers to interpret and comply with the general statement as written.

84.228 Air velocity and noise levels; hoods and helmets

The title of the section is air velocity and noise levels, however, nothing is said about air velocity. A test method should be defined to eliminate ambiguity.

84.229 Procedure for Statistical Analysis

NIOSH is using a three or six sample method of analyzing data to assure compliance with test requirements. However, no explanation is given why this sample size was selected. 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 size. The method proposed by NIOSH puts an undue burden on the manufacturer because of the high beta error involved. In addition, it is arbitrary to use sample sizes of 3 and 6, especially since the manufacturer is doing the testing and should be allowed to test as many samples as necessary to demonstrate capability to meet

the performance requirement.

Change (e) to read: If the initial sample of three (3) fails to demonstrate performance at the required level of confidence, additional samples shall be tested and m, s, and UTL or LTL shall be recalculated for the total sample using K from the following table:

n	K	n	K
3	6.158	11	2.275
4	4.163	12	2.2310
5	3.407	13	2.155
6	3.006	14	2.108
7	2.755	15	2.068
8	2.582	16	2.032
9	2.454	17	2.001
10	2.355	18	1.974

If at any point acceptable performance is demonstrated, the performance test may be terminated.

Note: This table was taken from Juran, "Quality Control Handbook, Third Edition, Appendix II, Table V".

If additional samples fail to demonstrate acceptable performance at the 95% confidence level after 18 samples, the respirator under evaluation shall be considered unacceptable.

For example, if a particulate respirator were tested that was

intended to meet the new proposed class I requirements of 10% maximum penetration and the results obtained from 3 tests were 2%, 4% and 6%, the respirator would fail to meet the proposed new criteria using the NIOSH formula where: m = mean = 4%

s = standard deviation = 2

k = tolerance limit factor = 6.158

$$UTL = (m + ks)$$

$$= 4 + (2 \times 6.158)$$

$$= 16.316$$

The prediction indicates the maximum penetration could be 16.3% which is above the NIOSH maximum allowable 10% penetraiton. The NIOSH procedure requires an additional 3 samples be tested. For this example, let's assume the next 3 results are even better: 1%, 2% and 6%. Now: m = mean = 3.5

s = standard deviation = 2.17

k = 3.006

$$\text{or } UTL = 35 + (2.17 \times 3.006)$$

$$= 10.1\%$$

Even though the average is dropped to 3.5 and the maximum observed reading is still 6, the NIOSH method would predict the maximum penetration is 10.1% and the respirator would fail the certification requirements even though the maximum observed penetration was only 60% of that allowed. As the sample size increases to about 18, the value of k decreases because of greater certainty in the prediction.

Manufacturers should be allowed to require maximum certainty that their request for submission will not be erroneously rejected.

Subpart R - Face Seal Leakage

84.231 General

(b) NIOSH defines face seal leakage as all sources of leakage except filter penetration. In testing air-purifying respirators for face seal leakage, NIOSH states the highest efficiency particulate filters compatible with the respirator shall be used. The effect of filter penetration on the face fit may then be eliminated analytically if filter penetration is still not negligible. However, NIOSH does not state how one is to analytically remove filter penetration from face seal leakage determinations. In order to comment on this requirement, the method must be known.

Past experience shows that the filter penetration rate varies with breathing rates and patterns. Since breathing rate and patterns vary from individual to individual, it is very difficult to arrive at a single meaningful correction factor for filter penetration. For this reason, we recommend all respirators be tested for total inward leakage, not just allowed face seal leakage. No correction for filter penetration would be needed. Accordingly, we have recommended performance criteria for approval under section (j) below, for total inward leakage for four classes of respirators by filter type. These values can be measured directly with no corrections necessary.

(c) NIOSH states that gas and vapor type respirators shall be evaluated for face seal leakage with high efficiency particulate

filters in place. However, it is not possible to evaluate a gas-vapor "single use" type respirator if a high-efficiency filter is not available in a "single-use" configuration. Also, assuming both single use configurations are available, one cannot assume that the mask-to-face interface is identical for both configurations.

84.232 Negative pressure respirators, either air-purifying or atmosphere supplying respirators

(a) Sizing. NIOSH is requiring the manufacturer to specify a range of facial sizes the respirator is intended to fit based on two face measurements: face length, from the menton to the nasal root depression, and face width, the bizygomatic breath. The respirator will then be tested on a group of people whose 2 facial measurements fall within those size ranges (see section (b) panel selection). A subsequent paragraph, paragraph (i) "Marking", states each facepiece shall be marked to indicate the range of facial sizes it is intended to fit.

NIOSH appears to be implying with this approach to respirator sizing and marking that the test will be a useful predictor of fit for any individual whose two facial dimensions fall within the range specified by the manufacturer. But most experts agree that the face length and width are not the primary determinants of facepiece fit. Many other facial features effect respirator fit. Thus, marking respirators with these dimensions may encourage a false sense of confidence about fit and discourage fit testing. No test on a panel

can ever take the place of performing a fit test on each individual for every respirator they will wear.

This requirement should be aimed at preventing respirators with inherently poor fitting capability from being certified, i.e., those respirators that can be expected to consistently fail to provide an acceptable fit to most wearers. An alternative scheme to NIOSH's approach to respirator sizing and marking is proposed below under (b) "Panel Selection".

(b) Panel Selection. NIOSH states each facepiece shall be tested on a panel of 25 adult individuals with face sizes within the range of dimensions specified by the manufacturer. In addition, the distribution of facial sizes within the panel shall approximate the distribution of facial sizes of the general adult population per the Los Alamos panel. It is difficult to comment on this requirement because NIOSH has not made it clear whether the procedure proposed for sizing and testing respirators applies to each size of a facepiece or all sizes of one facepiece.

We propose an alternate scheme for sizing respirators and testing respirators' fit capability on human subjects:

I. Single or multiple sizes designed to fit the general workforce.

1. Compose a 25 person panel per the Los Alamos grid.
2. If more than one size is available, the subject shall choose the size that is most comfortable. If that size fails to fit, other

sizes will be tried. The value from the best fitting size will be used to determine passage or failure of the test.

3. Respirators shall fit a minimum of 90% of the panel members by using single or multiple sizes for determining compliance with the requirement.
4. Respirators will not be marked according to size using the grid.

II. Single or multiple sizes designed to fit a particular segment of the population.

If a manufacturer chooses to develop a mask for a specific segment of the population, such as orientals, people with small faces, etc., the manufacturer shall so specify on the application for certification the facial attributes the respirator is designed to fit. The respirator shall be evaluated as follows:

1. Compose a 10 person panel of subjects from the specified population.
2. If more than one size is available, the subject shall choose the size that is most comfortable. If that size fails to fit, other sizes will be tried. The value from the best fitting size will be used to determine passage or failure of the test.
3. Respirators shall fit a minimum 90% of the panel members by using single or multiple sizes for determining compliance with the requirement.
4. The respirator manufacturer shall have the option of marking the respirator as tested and certified for the particular segment of the population.

(d) Spectacles. For clarity the term "evaluated" should be replaced with "fit-tested".

(f) Exercise Regimen. First, ANSI Z88.10 has concluded that exercises of 30 second duration provide the same assurance of fit measurement as do 1 minute exercises. Reducing the exercise duration to 30 seconds also greatly reduces the testing burden associated with evaluating facepieces on 25 individuals for a face seal determination. Reducing the exercise duration reduces the testing time per person from approximately 12 minutes down to 6-1/2 minutes. For a 25 person panel, this results in a savings in excess of 2-1/2 hours of valuable test equipment and technician time.

Second, it is inappropriate to include "grimacing or frowning" as one of the test exercises. It is difficult to comment on this since NIOSH provides no explanation or justification for its inclusion anywhere in the preamble to the proposed rule. In the past, this exercise was used by Los Alamos National Laboratory and others as a means of purposefully inducing a face seal leak, then checking for ability of the mask to reseat and reseal on the wearer's face. It is an impossible exercise to standardize or perform repeatedly in the same manner by the same person. Moreover, averaging leakage results from an exercise designed to induce a face seal leak, into a test designed to measure sealing capability, is meaningless.

(h) Analysis. NIOSH is proposing to require manufacturers to first compute the lower fifth percentile of the average inward leakage

during nine exercises, for the 25 people comprising the panel, then apply an added factor of statistical conservatism in the form of 95% confidence limits, before they can demonstrate compliance with the requirement for allowable face seal leakage. Measuring fit factors on a 25 person panel is too highly variable to suggest application of statistical confidence limits. For example, in addition to choosing a very wide range of face sizes by the 2 dimensions of length and width in selecting people for the panel, the multitude of other dimensions affecting fit will also vary randomly. Thus, one would expect a large range in fit values.

(j) Performance Criteria. To our knowledge, there is no practical method to subtract the filter penetration from this test to show the total inward leakage. We suggest that the terms low, medium and high efficiency should not be used because these are misleading to respirator users. Instead, we recommend Class I, II, III and IV be used. We have revised the Table to reflect the change in nomenclature and in Allowed Inward Leakage.

In view of the above, we recommend that this be a pass/fail test with a maximum allowed failure rate of 10%, i.e., 10% of the panel are allowed total inward leakage in excess of the values listed below for the four classes of respirators by filter efficiency.

Allowed Inward Leakage

for Particulate Respirators

Facepiece

Type	Class I	Class II	Class III	Class IV[a]
Quarter	0.2	0.1	0.02	0.01
Half	0.2	0.1	0.02	0.01
Full	0.2	0.1	0.01	0.01

[a] Applies also to atmosphere supplying and gas and vapor respirators.

We have deliberately removed "mouthpiece" from the table of requirements since these cannot be adequately probed.

We recommend a filter efficiency of 90% instead of 95% for Class II (previously termed low efficiency) respirator with particulate filters. Our rationale is explained in our Subpart V.

84.233 Positive pressure atmosphere supplying respirators

(a) To eliminate the testing of a positive pressure respirator in a negative mode, we recommend that (a) be changed to read: "...Facepieces used in combination negative/positive pressure atmosphere supplying...". In addition, eliminate the last sentence in (a).

(c) There should be a consistent safety factor applied throughout the positive pressure tests for the allowable inward leakage to be consistent with the minimum assigned protection factors.

84.234 Continuous flow atmosphere supplying respirators

By listing continuous flow atmosphere supplying respirators in a separate section, it is implied that a continuous flow respirator is not a positive pressure respirator. We do not agree with this severance and submit that if the performance requirements for continuous flow respirators do not assure positive pressure, then these requirements should be adjusted accordingly to assure that a positive pressure be maintained.

The required fit factors are not only excessively high (over 3000), but conflict with the protection factors in §84.32. Thus, the respirator is expected to achieve a much higher performance level in NIOSH certification testing than its assigned protection factor.

84.236 Mouthpiece respirators

This section is not subject to intelligent interpretation and therefore we ask NIOSH to clarify before committing to comment.

84.237 Reduced panel size

The first sentence of this section should include the words: "or specific characteristics" after the word sizes in the second line. This more accurately reflects the manufacturer's intent to design a respirators fit based on features other than facial sizes alone, such as Oriental nose bridges, predominant chins, etc.

The third sentence should end with "10.", with all remaining language in this section deleted. (See section 84.231(h) for explanation.)

Subpart S - Self-contained breathing apparatus

84.242 Interchangeability of oxygen and air prohibited; use of 100 percent oxygen in open flames and high heat

(b) NIOSH's intent here is to recommend against the use of these oxygen devices for fire fighting. However, this is the only type device currently available for mine rescue or long duration fire fighting. This is contrary to current practice. Moreover, OSHA and MSHA presently permit the use of these devices for such applications. Therefore, it is imperative that use of these types of devices continue as is.

Finally, respirator use falls within the jurisdication of other government agencies (OSHA, MSHA, NRC, etc) and not within the jurisdication of NIOSH.

84.243 Compressed breathing gas and liquefied breathing gas containers

(d) This section refers to compliance with ANSI Standard B57.1-1965. This has been replaced with a new 1987 version (CGA V-1, 1987) and should therefore replace the 1965 standard contained in this proposed section.

84.246 Hand-operated valves

(c) Because some valves have "on-off" functions rather than incremental adjustments, this section should be changed by deleting the words "readily adjusted" with "readily operated".

84.247 Breathing bags

(b) The requirement that the breathing bag be flexible is ambiguous and not subject to objective evaluation. Therefore, the word "flexible" should be omitted.

(c) Similar to (b) above, the requirement that the breathing bag be protected from "damage" or collapse by "external forces" is so ambiguous that one cannot determine whether this requirement is being met. Thus, we submit that this entire section be deleted.

84.248-4 Weight markings

Marking the fully charged and discharged weight permanently and legibly on each SCBA is not a feasible requirement. It is not possible to meaningfully comment on this paragraph since NIOSH has not stated why they have included this requirement. Nonetheless, even as stated, this requirement would be virtually impossible to comply with. Respirators are approved for use with many accessories or options. Each time an accessory or option is added or removed, weight changes occur. Some can be very significant, such as switching from a steel to an aluminum cylinder. In addition, the

components themselves vary a great deal in weight from one to another. For example, one steel cylinder might vary 2 pounds from another of the same type.

The certification standard should be a performance standard and not a design standard. Weight is a design parameter and should not be specified.

84.248-5 Breathing resistance test

(a)(2) This requirement should apply to both positive pressure open and closed circuit apparatus.

Recording instrumentation sensitivity, accuracy and response time must be specified in order to provide NIOSH and the manufacturers with uniformity and repeatability of test results.

(c) Static pressure, i.e., assessing breathing resistance when not breathing, is not a significant aspect of the apparatus' performance. Therefore, the tests for "positive pressure (above static)" and "static pressure (no flow)" should be removed.

84.248-7 Bypass gas flow test

(a)(4) The user should be able to adjust the bypass flow rate to any level so long as the bypass valve delivers at least 85 lpm should the

user fully open the bypass control. The last sentence of this section should refer to paragraph (5) rather than (e).

84.248-9 Service time test; Closed-circuit apparatus

(a) and (b) Requiring the use of man tests to measure service time is too variable. The technology exists to perform these tests using machine tests (metabolic simulators) which would give more consistent results.

84.248-11 Tests during low temperature operation

(e)(1) This section requires that the apparatus "function satisfactorily", but does not define what level of performance is needed to comply with this provision. Therefore, performance requirements must be proposed before any meaningful comments can be made.

(f) This section should be changed to read: "...are commercially available and recommended by the manufacturer for use on this device". NIOSH has in the past and should continue to approve parts this way.

84.248-12 Shock and vibration tests

The latest revision to MIL standard 810 is Revision D dated July 19, 1983 and it contains no callout for rubber tired vehicles. Therefore, the proposed protocol for the vibration test is not appropriate and does not reflect the provisions in the current MIL standard. Therefore, a new method to measure endurance against vibration should be developed. Further, it is not clear from the proposal if the apparatus is to be operated during the vibration test. If it is, respiration rate or tidal volume must be specified for the breathing machine test.

How the apparatus is to be mounted for the vibration test should be specified due to the wide variety of industries in which the equipment is used. In addition, the mounting of the apparatus in use is normally determined by the user.

(a) This section states that the device shall be machine tested at 60 lpm. However, service performance requirements are set at either 40 lpm on a breathing machine or 300 lpm constant flow which is consistent with 248-6(a)(2) and 248-8(a). The 60 lpm requirement should be dropped and replaced with these limits. The requirement should also be brought in line with NFPA 1981, "Self-Contained Breathing Apparatus For Fire Fighters".

(b) The shock test should be eliminated due to inherent variability of such tests.

(d) "The vibration test shall be performed..." should be reworded to cover deletion of the shock test. Finally, the testing should be

performed on a metabolic simulator, not on human test subjects.

84.248-13 Use tests; Purpose and requirements; General

(b) We recommend the use of metabolic simulators instead of human test subjects in order to assure consistent results.

84.248-14 Use Tests, Table 1 Man Test 1

Footnote a states to repeat the 1 hour test for 2, 3 and 4 hour service times.

It is not clear how many times to repeat the 1 hour test. In 30 CFR Part 11, the test was repeated once for each hour of duration. This would be our recommendation.

84.248-15 Use transfer test

This section requires that the transfer from air-line to SCBA be conducted within 15 seconds. The test subject, however, is restrictd to only having read the manufacturer's instructions before performing this rapid changeover procedure.

It is suggested that in addition to reading the instructions, the test subject be allowed to practice the procedure to obtain some

degree of familiarity prior to running the transfer test. These respirators are to be part of a respiratory protection program where users should be given this type of practice prior to respirator use.

84.248-16 Use tests; Requirements

(b) The requirement that the respirator not cause undue discomfort to the wearer is vague and should be eliminated. In addition, this test should be done on a mannequin using a metabolic simulator because there is too much variability from wearer to wearer. An objective method of measuring fogging should be established.

84.248-17 Flammability

The proposed standard includes a test which exposes a respirator facepiece to flame while sealed to a mannequin head.

This test is unrepresentative of respirator use conditions and is potentially design restrictive. Self-contained breathing devices are not intended for direct flame contact. It cannot be determined which part of the respirator may be contacted by the flame. Therefore, a flammability test of the respirator should be designed to expose the entire respirator uniformly to heat/radiant flux. The respirator should be mounted on a mannequin and operated by a breathing machine during this exposure. The criteria should be limited to continued operation of the respirator, non-separation of

the respirator from the mannequin and no after flame of the respirator. The current test is design restrictive because it does not require the respirator to continue to operate during and after the flame exposure and may encourage respirator designers to locate components which they believe to be sensitive to flame contact on portions of the respirator remote from the facepiece in an effort to avoid failing this test.

84.248-17 Scheme of test rig for flammability (figures)

This section should be eliminated in accordance with the above comments. As presently proposed, the following comments are made:

Detail 2 must illustrate each component with a label in order to properly align the burners with the facepiece.

The burner size or a brand must be specified to allow duplication of test results. Additional dimensions would be required to allow accurate positioning of each facepiece.

Subpart T - Air-Line Respirators

84.250 Air-line respirators; Description

The third sentence of this section refers to a 'single stage' regulator. 'Single stage' should be deleted and substituted with 'pressure reducing'. Restricting the use of regulators of the 'single stage' design is too limiting and unnecessarily eliminates other types of pressure reducing regulators.

The comma at the end of the sixth line should be deleted.

84.251-1 Air-line respirators; Regulated flow and

84.251-2 Air-line respirators; Continuous flow

Section (b) should be removed from both paragraphs. Section 1(a) should apply to both regulated and continuous flow air-line respirators.

Both Sections specify a 125 psi maximum allowed hoseline pressure.

There is no reason for a limit of 125 psi for supply pressure. Hose with working pressures higher than 125 psi are common. Higher pressure could also allow more versatility in respirator design.

84.251-3 Air-supply tests

(a) Delete this Section. It is design restrictive to limit the length of hose and the number of multiples. No reason has been provided to require minimum or maximum hose length requirements.

(b)(1)(2) For demand and pressure demand air-line regulators, maximum available flow should not be limited to 425 lpm. SCBA demand and pressure demand regulators are presently not limited in airflow and therefore, air-line respirators should not have such limitations. In addition, continuous flow hood-helmet devices should not be limited. If the self-generated noise is not in excess of 80 dBA, limiting maximum flow is an unnecessary design constraint. For continuous flow rates in excess of 425 lpm, wearer comfort is not necessarily compromised. Consideration should be given to raising the minimum flow rate for continuous flow respirators by testing with a breathing machine to be assured that positive pressure is maintained.

(b)(2) This section should be deleted and replaced with 84.248-6 (a), (2) and (3). The following should be added: "Breathing resistance shall comply with the requirements of 84.248-5 for open circuit devices".

Users expect and depend on demand and pressure demand air-line respirators to perform the same as SCBA and therefore the performance requirements should be the same.

(c) A cycling test for SCBA demand and pressure demand type regulators should be added. SCBA pressure demand types are approved

for use in IDLH atmospheres, while air-line pressure demand and demand devices are not approved for use in IDLH atmospheres.

This section also requires that the regulator shall be connected to "a source of intermittent suction". It is not clear what this means. Therefore, if a breathing machine test is required, then specific parameters must be provided.

84.251-4 Harness test

(f) That portion of this section requiring either the harness or the hose to attach to the wearer's clothing is unclear and meaningless since neither harnesses nor hoses attach to clothing. Without more clarity, further comment is impossible.

84.251-5 Breathing tube test

(a) The requirement that a pull on the breathing tube will not "disturb the wearer" should be removed. It is too ambiguous and meaningless.

(b) and (c) These Sections are superfluous and design restrictive.

84.251-7 Airflow resistance test; Air-line respirator, negative pressure class and

84.251-8 Airflow resistance test; Air-line respirator, positive pressure class

The requirements in these Sections should be made consistent with those for self-contained breathing apparatus requirements described in 84.248-5, with the possible exception of loose fitting hoods and helmets due to the inherent differences in operating characteristics of these devices.

Subpart U - Air-purifying Respirators; General Requirements

84.262 Filters used with canisters and cartridges; Location; Replacement

(a) The wording in this section should be revised as follows: "Particulate filters used with a gas and vapor canister or cartridge shall be located so that a gas and vapor removing element is located downstream of the particulate filter. In some cases, it may be necessary to place an additional gas or vapor removing element at the inlet side to protect the particulate filter."

84.263 Powered air-purifying respirator flow requirements

Consideration should be given to raising the minimum flow rate for continuous flow respirators and test with a breathing machine to be assured that positive pressure is maintained.

Subpart V - Particulate Air-Purifying Respirators

84.270 Particulate air-purifying respirators; Description

(a) The opening sentence of this section should be changed to reflect that particulate filters remove solid and/or liquid contaminants rather than solid and liquid contaminants. The need for respiratory protection against solid particulates accounts for more than 90% of particulate respirator use. The classification of a particle in the workplace as to whether it is a liquid or solid is an easy determination. Respirator filters designed to work effectively against solid particles will not necessarily work well against liquid aerosols. For those filters employing filter media whose efficiency is enhanced with electrostatics, the liquid will wet and coat the media, insulating the charge from the particle much like insulation on a wire, causing lower filter efficiency. Many of the respirator filters used today employ electrostatics. Likewise, a filter designed for liquid particulates does not perform well against solid particles. Filters not incorporating electrostatics generally load rapidly increasing breathing resistance, making the respirator less acceptable to the worker and requiring more frequent filter replacement. Face seal leakage will also increase proportionate to the increase in breathing resistance. Overall, this requirement as proposed will lead to less acceptable and more costly respirators which will offer lower protection. Thus, this minor change from "and" to "and/or" is a significant and necessary amendment.

(c) As suggested in 84.232 (j), we recommend a classification of

particulate respirators using Class I, II, III and IV, not low, medium and high efficiency. Filter efficiencies for these classes should be 80, 90, 99 and 99.97 respectively. Use of the term "low efficiency" filters implies inferior protection and this is not necessarily the case. Use of this type of classification would also be consistent with the International Standards.

(e) Finally, a new section (e) should be added as follows: "Particulate respirators shall be classed according to whether they are designed for solid or liquid particles or both." (See (a) above.)

84.273 Particulate instantaneous penetration filter test

Change the opening sentence to read that filters shall be tested against solid and/or liquid particles, rather than both solid and oil liquid particles. See explanation in 84.270(a) above.

(b) This section proposes that the penetration tests be performed "immediately" after preconditioning. This is simply an impractical requirement to physically carry out. We therefore recommend the test be conducted within 18 hours after conditioning which is the same requirement proposed for the chemical cartridge test.

(e) Delete the last sentence in (e) and all of subparts (1) and (2). These sections refer to using a breathing machine but since this is a filter test, it makes no sense to use a breathing machine on a continuous flow powered air-purifier.

Subpart W - Gas and Vapor Air-purifying Cartridge Respirators

84.280 Gas and vapor air-purifying cartridge respirators; Description

(a) NIOSH has lowered the maximum use concentration (MUC) of methylamine to 75 ppm and has not stated the reasons why. The MUC should remain at 100 ppm where it is currently set. It is difficult to comment on this section without NIOSH's rationale for this reduction.

The MUC table in this section lists certain chemicals and their MUC, and yet the respirator descriptions in (a) refer to their use against classes of chemicals. But nowhere is a class of gases or vapors defined. Moreover, as proposed, the table does not even include those substances which NIOSH uses as a test agent, such as formaldehyde.

(c) This paragraph should be deleted since it relates to intended respirator uses, not certification and testing. Respirator use falls within the jurisdiction of other government agencies (NRC, OSHA, etc.) and outside the testing and certification jurisdiction of NIOSH.

84.283 Breathing resistance test

Here, NIOSH specifies final breathing resistance requirements for gas and vapor filters. However, since NIOSH has recognized the inapplicability of final breathing resistance measurements for

particulate respirators as not relating to respirator performance, we suggest that this requirement be similarly dropped for gas and vapor respirators.

84.284 Gas and vapor cartridge service life test

The proposed requirement that the cartridges be tested within 8 hours of preconditioning is impractical to comply with and adds nothing of significance to the test. Further, if the preconditioned cartridges were sealed in a 1 quart air-tight container with dry air, they would lose no more than 1/2% of the moisture absorbed. This would have negligible effect on the service life. Thus, the current requirements for preconditiong and testing should be maintained. (See specific comments at 84.308.)

Subpart X - Gas and Vapor Air-purifying Canister Respirators

84.290 Description and classification

(a) It is stated that a half facepiece canister respirator can be used only for escape purposes. It is unclear whether this includes both IDLH and non-IDLH environments. This statement needs clarification.

(d) This paragraph should be deleted since it relates to intended respirator uses, not certification and testing. Respirator use falls within jurisdiction of other government agencies (NRC, OSHA, etc.) and outside the testing and certification jurisdiction of NIOSH.

84.293 Breathing resistance test

Here, NIOSH specifies final breathing resistance requirements for gas and vapor filters. However, since NIOSH has recognized the inapplicability of final breathing resistance measurements for particualte respirators as not relating to respirator performance, we suggest that this requirement be similarly dropped for gas and vapor respirators.

84.295 Canister service life test

(a)(b)(c) The proposed requirement that the cartridges be tested

within 8 hours of pre-conditioning is impractical to comply with and adds nothing of significance to the test. (See comments on 84.284.) Thus, the current requirements for preconditioning and testing should be maintained.

The test conditions in table 6 for carbon monoxide at a concentration of 20,000 ppm references both footnotes b and d. The temperature requirement in these 2 provisions are different and therefore impossible to comply with. Reference to Footnote d should be deleted.

(f)(3) The requirement that the indicator change within 80 $\pm$ 10% of the total service life is in conflict with Section 84.314(a) of Subpart Z. That section requires the indicator shall change or afford such warning less than or equal to 90% of the total service life. This section should be changed to be the same as Section 84.314(a) and require the indicator change at less than 90% of the total service life.

Subpart Y - Organic Gas and Vapor Air-purifying Cartridge and Canister Respirators

84.300 Description and limitations

This section should be deleted since it relates to intended respirator uses, not certification and testing. Respirator use falls within the jurisdiction of other government agencies (NRC, OSHA, etc.) and outside the testing and certification jurisdiction of NIOSH.

84.302 Organic gas and vapor air-purifying canister respirators

(a)(2) Reference to use of mouthpiece/noseclamp half-mask gas masks is unclear and needs to be clarified. It is unclear if this means escape from IDLH or non-IDLH atmospheres.

84.303 Labeling requirements

It will be extremely difficult for manufacturers to indicate all organic vapors and gases for which their respirators will provide adequate protection. Such a provision will create numerous problems and is not currently required. First, it would take manufacturers many years to test even the most common chemicals (the number of common chemicals in the workplace far exceeds 1,000) for their respirators. This would therefore leave certain end users without any protection for that period of time. Second, there are many

chemicals which are not widely used but where an organic vapor respirator may be useful. Those chemicals would not normally be used as a test challenge medium by the manufacturer, yet they might have been tested and successfully used adequately by end users. Under the proposed labeling requirement, the end user might be left without a reasonable alternative since he could not use such a respirator without the manufacturer's approval.

In addition, nearly all organic vapors and gases occur as mixtures and to test against only one of the components provides little useful information.

The best method for evaluating a cartridge's performance against a specific organic vapor and gas is in the workplace where the mixtures and environmental conditions in which they will be used are present. This is best done by the user.

Finally, NIOSH must delete the requirement to label these respirators with a list of all the organic vapors and gases having good warning properties for which the respirator is effective. This places an unnecessary burden on the manufacturer to test and certify respirator performance in this manner since those substances with good warning properties automatically notify the wearer (assuming the wearer has passed an odor sensitivity test) of contaminant breakthrough. However, for those substances without good warning properties, specific field tests should be required and so labeled by the manufacturer.

(b) This paragraph should be deleted since it relates to intended respirator uses, not certification and testing. Respirator use falls within the jurisdiction of other government agencies (NRC, OSHA, etc.) and outside the testing and certification jurisdiction of NIOSH.

84.306 Breathing resistance test

Here, NIOSH specifies final breathing resistance requirements for gas and vapor filters. However, since NIOSH has recognized the inapplicability of final breathing resistance measurements for particulate respirators as not relating to respirator performance, we suggest that this requirement be similarly dropped for gas and vapor respirators.

84.307 Particulate tests; canister and cartridge containing filters

Provision for combination escape respirators using an air-purifying mode should be included since NIOSH has allowed approvals of these under the current standard. An air-line respirator, used in an air-purifying mode only for escape, should not have to meet resistance requirements as an air-purifying respirator. Instead, the applicable breathing resistance requirements of Subpart T should apply.

84.308 Service life test

The proposed requirement that the cartridges be tested within 8 hours of pre-conditioning is impractical to comply with and adds nothing of significance to the test. (See comments at 84.284.)

We also strongly recommend maintaining the following requirements: Test at 25 ± 1°C and 50% ± 2% RH with flow rate at 32 lpm for conditioned samples or 64 lpm for as received samples. Condition at 25 ± 1°C and 25 or 85 ± 2% RH. No organic vapor chemical cartridge currently available in the US today will meet this requirement. Organic vapor chemical cartridges will have to be made about four times bigger to meet this requirement with today's technology. Moreover, respirator users have not expressed the need for longer service life OV cartridges.

84.314 Requirements for end-or-service-life indicators

Listing requirements that an end of service life indicator must meet is premature and should be deleted. Few, if any, indicators are in existence today. Pre-existing limitations in the requirements stifles innovation. For instance, the requirement that the wearer be able to see a passive end of service indicator is not necessarily of value.

For example, if the cartridge service life is sufficiently long to assure that during its use the respirator will be removed, the wearer will be able to see the indicator long before breakthrough occurs.

An example of this would be a cartridge whose service life lasts 200 hours at its maximum use limit. If its indicator changes at 90% of the service, the user would have 20 hours to view the indicator change before breakthrough occurs.

Appendix A - Assumed Conditions of Use

(f) NIOSH states "Gas and vapor cartridge respirators will be used in concentrations in excess of the maximum use concentration". It is unclear why NIOSH should make this assumption when such use is prohibited by regulation. NIOSH should clarify their intent or delete the Section because it acknowledges and tacitly condones misuse of respirators.

(j) This paragraph is redundant with Section (g) which covers air quality of atmosphere supplying respirators and can thus be eliminated. In addition, Section (j)(2) contains a reference to paragraph (c) that is not pertinent to atmosphere supplying respirators. It is not known for what paragraph, if any, the reference is intended.