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ISEA Industrial Safety Equipment Association

April 11, 1995

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OSHA Notice of Proposed Rulemaking on Respiratory Protection, 29 CFR Part 1910

The Industrial Safety Equipment Association (ISEA) is pleased to submit the enclosed comments on behalf of its Respiratory Protection Group. The members of this group are as follows:

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E. D. Bullard Company
Cabot Safety Corporation
Glendale Protective Technologies Inc.
Louis M. Gerson Company Inc.
Hornell Speedglas Inc.
International Safety Instruments Inc.
3M Company
Mine Safety Appliances Company
Moldex-Metric
North Safety Equipment
Pro-Tech Respirators Inc.
Racal Health and Safety Inc.
Scott Aviation
Shalon Chemical Industries
Survivair Inc.
U.S. Safety
Uvex Safety
Willson Safety Products

If you have any questions on these comments, please contact William J. Erny, ISEA Technical Director.

Sincerely yours,

Daniel K. Shipp
President

Enclosure

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Comments of the
ISEA Respiratory Protection Group
to the Occupational Safety and Health Administration

Respiratory Protection, 29 CFR 1910.134

April 13, 1995

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Executive Summary

The Industrial Safety Equipment Association (ISEA) supports the efforts of the Occupational Health and Safety Administration (OSHA) to update and revise the requirements in its existing respiratory protection standard, 29 CFR 1910.134. We also support OSHA's recognition that any alleged deficit in the protection afforded by products meeting only the current OSHA standard is the result of shortcomings in the standard itself rather than deficiencies in respirator quality, as well as the agency's recognition of the importance of this distinction in the discussion of risk and reduction of risk.

ISEA looks forward to continuing to work with OSHA to complete this rulemaking and offers its technical resources and expertise to help advance the standard. In the attached comments, the association identifies the strengths of the rule and recommends specific changes to the proposal that we believe will make the standard more effective and its requirements more realistic. Specifically, ISEA's comments focus on three areas:

- addressing OSHA's failure to adhere to the consensus of respiratory protection experts embodied in American National Standards Institute (ANSI) Standard Z88.2 1992;
- clarifying when full medical evaluations and mere medical questionnaires should be required in the proposed rule; and
- eliminating the shortcomings in the proposed fit testing requirements.

ISEA has long advocated OSHA adoption or incorporation of voluntary consensus standard ANSI Z88.2-1992. Such a step is supported by the White House Office of Management and Budget (OMB) directive embodied in OMB Circular A-119, which requires federal agencies to follow existing voluntary consensus standards when adopting those standards would achieve the purpose of the agency rulemaking and would eliminate unnecessary and redundant uses of agency resources.

ISEA objects to OSHA's use of obsolete statistics to justify the revisions to its standard, especially the data on which OSHA based its decision to adopt the outdated assigned protection factors (APFs) in the National Institute for Occupational Safety and Health's (NIOSH) 1987 Respirator Decision Logic. OSHA ignored current data supporting the APFs in ANSI Z88.2-1992, despite ISEA's repeated submission of that data to the Agency. If OSHA does not adopt the ANSI protection factors until after NIOSH issues its module on APFs, the agency should at least delay issuance of the final rule until after NIOSH publishes the APF module.

Many of the definitions in the ANSI standard better reflect current practices and modern technology. ISEA also recommends that OSHA adopt ANSI's requirements for respirator use against gases or vapors that lack adequate warning properties; its procedures for dealing with oxygen-deficient atmospheres; and its performance language requiring that users be able to select a respirator from an appropriate number of sizes and models.

OSHA should adopt medical evaluation alternative number three, as proposed. The rule should not include a minimum period of exposure that would trigger a requirement for an examination. On the other hand, OSHA should require that employers administer a health questionnaire to all respirator wearers and perform a full medical evaluation not only on those whose responses indicate the need for an evaluation, but also any end user who wears a self-contained breathing apparatus (SCBA) for emergency or rescue operations. If medical evaluations become mandatory, then the agency should implement a sliding scale of examinations. Lastly, when an employee is found to be unable to wear a tight fitting or negative pressure respirator for medical reasons, OSHA should require employers to ensure that all appropriate types of currently available respirators, including PAPRs and supplied air respirators, have been made available as possible alternative sources of respiratory protection.

OSHA should adopt the fit test validation procedures in the September 17, 1989, draft of ANSI Standard Z88.10, *Respirator Fit Methods*[1] and should permit any technical organization that generates adequate, scientifically valid data to recommend to the agency any alternative fit tests they have validated. In addition, the TSI Portacount and other validated fit test methods should be included in the respiratory protection rule. Any new qualitative fit tests (QLFTs) should perform at least as well as the current one; OSHA should not establish more stringent requirements.

OSHA should allow the use of the isoamyl acetate qualitative fit test for full facepiece respirators if the test concentration is raised to ten times the concentration used for half masks. In addition, the grimace exercise requirement is not appropriate for QLFT fit tests and should be removed.

For quantitative fit tests (QNFT), one test – rather than three - is sufficient to determine whether the minimum required fit factor is obtained.

OSHA is correct to require that fit testing be performed at least annually and should be coupled with retraining. Employers should be required to retain records of all training provided to each employee and be allowed to certify that fit testing was a part of that training. In addition, users should be required to

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[1] See attachment #4, September 17, 1989, draft of ANSI Standard Z88.10

follow the manufacturers' instructions for maintenance and calibration of quantitative fit test equipment.

ISEA would like to maintain open communication with OSHA in the development of this and future rulemakings. Research and development requirements and laboratory time are significant and costly for the manufacturing community. A close, functional working relationship between manufacturers and regulators will help reduce costs to the market that often result from unrealistic performance requirements and help expedite the placement of advanced products on the market through focused research and development.

I. Introduction

The Industrial Safety Equipment Association (ISEA) is the leading national organization of manufacturers of personal protective equipment and clothing. Since its founding in 1933, ISEA has been dedicated to protecting the health and safety of all workers, including those at factories, construction sites, farms, and health care facilities. Among ISEA's 72 member companies are 18 manufacturers of respiratory protection products, including all of the product categories that would be affected by 29 CFR 1910.134.

The association, whose members produce more than 95 percent of the respirators manufactured in the United States, has been an ongoing participant in the attempts of the Occupational Safety and Health Administration (OSHA) to revise its existing respiratory protection standard. ISEA's involvement with the standard began when it was issued by OSHA in 1971 and has continued through the notice of proposed rulemaking that appeared in the November 15, 1994, *Federal Register.*

More than a decade of OSHA's time and resources has been spent bringing the respiratory protection standard to this stage in the rulemaking. In addition to OSHA's own resources, industry and organized labor also have contributed significant time and energy to the rulemaking process. ISEA's goals with regard to 29 CFR 1910.134 are to (1) promote a rational respiratory protection standard that accurately reflects modern science and technology, (2) preclude the potential adverse market effects of a confusing and controversial rule, (3) eliminate inefficiencies in the rulemaking process that waste both public and agency resources, and (4) make use of existing national consensus standards, where applicable.

II. ISEA Supports OSHA's Efforts to Revise 29 CFR 1910.134

The members of ISEA support OSHA's efforts to publish an updated standard for respiratory protection. A revised standard should reflect the state-of-the-art in respirator technology and modern concepts of what constitutes a proper respiratory protection program. Such a rule would provide manufacturers, employers and end users with clear, succinct and feasible selection and use criteria enabling them to develop and implement effective respiratory protection programs. Revision of the respiratory protection standard, which is codified at 29 CFR 1910.134, is long overdue.

Since OSHA first announced its intention to revise its respiratory protection rule, ISEA has worked with the agency to reach a consensus on proper respiratory protection requirements. Following publication of the original

advance notice of proposed rulemaking, ISEA submitted written comments and offered its considerable expertise as a technical resource for agency staff revising the current rule.

III. Respirators Are Critical to Worker Protection

Respirators are an invaluable component of any workplace health and safety program. ISEA recognizes the established hierarchy of controls in accordance with which an employer must look first to engineering controls to eliminate or mitigate occupational hazards. In certain situations, however, workplace conditions render engineering controls no longer feasible and require an alternative means of respiratory protection. This is especially true at many construction and other non-permanent worksites, as well as agriculture, mining, and maritime workplaces.

Where engineering controls fail to provide adequate protection or are not otherwise feasible, respirators and other personal protective equipment are recognized under the hierarchy of controls as an effective and less costly means of protecting employees against the dangers of the workplace. In other instances, equipment failure or routine maintenance operations may necessitate the use of respirators.

The degree of protection that a particular respirator provides is dependent upon a number of factors, including respirator performance, fit and maintenance, and user training. Protection also depends upon whether the respirator is worn and worn properly, and such real world factors as comfort, fit, cost, etc. Performance criteria are established in the respirator certification rule of the National Institute of Occupational Safety and Health (NIOSH), which currently is codified at 30 CFR 11. NIOSH is in the process of revising these criteria, which then will be recodified at 42 CFR 84.

Product performance must be combined with an effective and comprehensive respiratory protection program to ensure that end users receive the best protection possible. ISEA considers this rulemaking critical to the industry and to the end user. The member companies at ISEA share OSHA's goal of protecting workers from workplace respiratory hazards and see this proposal as a first step in bringing the agency's respiratory protection criteria up to date with modern practices, science and technology.

IV. ANSI Z88.2-1992 Reflects The State-of-the-Art in Respiratory Protection

American National Standards Institute (ANSI) Standard Z88.2-1992, entitled "Practices for Respiratory Protection," reflects the most recent consensus among respiratory protection experts. To assure that OSHA's revised standard reflects modern technology and the most up-to-date notions of respiratory protection, the proposed respiratory protection rule should adhere to the expert consensus embodied in the ANSI standard.

ANSI Z88.2-1992 is widely recognized as the state-of-the-art on the proper selection and use of respirators. The latest version of ANSI Z88.2 was completed after an intensive seven-year effort to update the 1980 version of this voluntary consensus standard. The ANSI committee that drafted the revised standard was composed of many of the country's leading experts in respiratory protection, including the following representatives of users, manufacturers, academia, and OSHA and other government agencies:

Organizations Represented	Name of Representative
American Conference of Government Industrial Hygienists	Darrel Douglas
American Gas Association	Phil Runge
American Occupational Medicine Association	Philip Harber
American Industrial Hygiene Association	Doane Lucio
American Iron and Steel Institute	Jack Masaitis
American Petroleum Institute	Chris Williams
American Welding Society	Carol Dupraz
Brotherhood Boilermakers	Perry Day
Edison Electric Institute	Joe Peri
Electronics Industries	F. X. Worden
Goodyear Tire and Rubber Company	J. Holthouser
GPU Nuclear	Earl F. Gee Jr.
Health Physics Society	David Steffes
Industrial Safety Equipment Association	Rich Grunberg
International Association of Fire Chiefs	Gary Briese
International Association of Fire Fighters	Richard Duffy
International Union of Brick Layers	Albert Couillard
Lawrence Livermore National Laboratory	Robert da Roza
Los Alamos National Laboratory	Bruce Reinert
Motor Vehicles Manufacturers Association	Sarunas Mingela
National Fire Protection Association	Bruce Teele

National Institute of Occupational Safety and Health	Nancy Bollinger
Rhone-Poulenc Inc.	Gerald Cooper
U.S. Bureau of Mines	J. G. Kovac
U.S. Coast Guard	K. Wahle
U.S. Consumer Products Safety Commission	Colin Church
U.S. Department of the Army	Stephan Graham
U.S. Department of Energy	Paul Wambach
U.S. Department of Labor	Ching-Tsen Bien
U.S. General Services Administration	Dennis Davis
U.S. Nuclear Regulatory Commission	James Wigginton

Importantly, the Office of the President of the United States has placed significant value on national consensus standards as regulatory standards. Following the terms and requirements established by recognized experts in ANSI Z88.2-1992 would conform to the mandate of Circular No. A-119, released by the executive branch's Office of Management and Budget (OMB). The OMB circular states that "It is the policy of the Federal Government in its . . . regulatory activities to: Rely on voluntary standards . . . whenever feasible and consistent with law and regulation pursuant to law." OMB's own rationale for encouraging such a course of action is that "the adoption of voluntary standards . . . eliminates the cost to the Government of developing its own standards."

OMB A-119 goes on to state that "[v]oluntary standards that will serve agencies' purposes and are consistent with applicable laws and regulations should be adopted and used by Federal agencies . . . ." Precisely this goal could be accomplished by OSHA if it were to adopt or at least incorporate the framework and requirements of ANSI Z88.2-1992, which is recognized as the state of the art for respiratory protection in the modern workplace.

V. Workplace Protection Factor Studies Demonstrate that Modern Respirators Adequately Protect Users

On March 21, 1991, ISEA submitted to OSHA a series of workplace studies that evaluated actual exposure to airborne contaminants for workers using respirators under normal workplace conditions. After discovering that this submission was not included in the rulemaking record, ISEA resubmitted these same studies on March 29, 1994. At that time, the association added three studies that were not part of the original submission, for a total of 25 studies.

The studies submitted by ISEA measure the concentration of contaminants in the workplace and interior breathing zone of workers using NIOSH-approved respirators. These studies demonstrate that respirators approved by NIOSH, when properly fitted and maintained, provide adequate protection to workers exposed to particulates well above the permissible exposure level (PEL) for the specific contaminants studied.

OSHA has continually resisted ISEA's attempts to provide scientific data to the agency. This fact was made evident by the lack of attention that the studies were given in the agency's latest proposal. Out of the 25 workplace protection factor studies submitted (twice) to OSHA by ISEA, eleven also were submitted independently by third parties. Despite these repeated attempts by various parties to have OSHA review these relevant studies, only six actually were referenced in the preamble. No mention of the ISEA work is contained in the preamble and it appears that 19 of the 25 workplace protection factor studies submitted by ISEA were ignored.

VI. Assigned Protection Factors and ANSI Z88.2-1992

Designating assigned protection factors (APFs) for particular respirators traditionally has been OSHA's responsibility. Under the current proposal, however, OSHA defers the authority to establish APFs to NIOSH. ISEA agrees that NIOSH is the appropriate agency to evaluate overall respirator performance under workplace conditions, and to determine APFs for the different respirator classes with input from respirator users and manufacturers.

As part of its effort to revise existing certification requirements, NIOSH will release a module on APFs. This module, however, will not be completed for several months, if not years. In the interim, OSHA must determine what APF scheme users should follow.

In the past, ISEA has recommended that OSHA adopt the APFs established in ANSI Z88.2-1992. The values in the ANSI standard represent the consensus among the country's leading experts on respiratory protection. In the proposed rule, however, OSHA dismisses ANSI Z88.2-1992 as unsubstantiated by science, despite ISEA's submission of the very science on which this standard is based. Nowhere in the preamble is any rationale given for OSHA's decision to ignore these studies. The agency has indicated in the past, however, that the studies lack credibility because they have not undergone a formal peer review process.

The agency has raised objections in the past to the ANSI standard-setting process and the recommendations that result, which OSHA alleges lack rationale and background documentation. OSHA has called for detailed discussion from ANSI on how its conclusions were reached, including references to and complete descriptions of the particular studies involved.

This supporting information is found in the minutes of the ANSI meetings and in the workplace protection factor studies submitted to OSHA. The same studies submitted by ISEA are the studies upon which the ANSI Z88.2-1992 committee members relied in developing the 1992 standard. The assigned protection factors developed in the ANSI standard, therefore, are supported by more than two dozen workplace and simulated workplace studies bearing directly on the assignment of protection factors for various types of respirators currently certified by NIOSH and in commercial use.

VII. OSHA's Decision to Follow the 1987 NIOSH Respirator Decision Logic is a Mistake

Rather than adopt the assigned protection factors in ANSI Z88.2-1992, OSHA's proposed respiratory protection rule states that, in the period between publication of the final rule and release of the NIOSH APF module, OSHA will defer to the protection factors assigned in NIOSH's 1987 Respirator Decision Logic. ISEA strongly objects to this decision. Deferring to the 1987 NIOSH decision logic will only serve to confuse end users, since most of the respiratory protection community currently follows the assigned protection factors in ANSI Z88.2-1992. OSHA should maintain what is effectively the status quo by enforcing the assigned protection factors in the ANSI standard until NIOSH has completed its APF module, which tentatively is scheduled to be the next module.

The OSHA decision to follow the 1987 NIOSH decision logic is misguided. Not only do most end users follow ANSI Z88.2-1992, which has more stringent requirements than the legal obligations found in the current OSHA rule, OSHA also fails to provide justification for its decision to follow the NIOSH APFs. These values are based on studies that were conducted in laboratories twenty years ago and their conclusions depend upon the results of simulated workplace testing. Significantly, many of these studies have never been subjected to peer review, the very problem that OSHA cites when discounting the weight of ANSI Z88.2-1992.

In the introduction to the Respirator Decision Logic, NIOSH itself recognizes the shortcomings of the research from which its APFs were derived and cautions readers that their ability to predict actual performance in the

workplace is unproven. NIOSH states that "[f]or the present, APF's should not be considered reliable predictors of performance levels that will be achieved during actual use, since APF's are not based on a sufficient amount of workplace testing."

Extensive workplace testing has been conducted in the years since NIOSH released the decision logic, and these tests form the basis of ANSI Z88.2-1992. NIOSH's own document, therefore, argues for OSHA adoption of the ANSI standard.

VIII. Adoption of the NIOSH Protection Factors Would Cause Undue Hardship And Provide Little or No Benefit to End Users

Most respirator users rely upon ANSI Z88.2-1992 as their guide for determining adequate respiratory protection. The current OSHA respiratory protection standard, however, is based on the 1969 ANSI Z88.2 standard. Over the years, respirator users have upgraded their programs repeatedly to be consistent with the most recent ANSI standard. It is interesting to note that OSHA's own compliance directives dealing with 29 CFR 1910.134, although they cite ANSI Z88.2-1969, have incorporated the requirements of each updated version of ANSI Z88.2. This amounts to de facto adoption of the revised standards by OSHA. Converting to another scheme as mandated by OSHA would be confusing to users, particularly when there is no scientifically rational basis for doing so.

Even if OSHA declines to adopt the ANSI Z88.2-1992 assigned protection factors, it would be unwise to require employers and end users to follow the APFs in the 1987 NIOSH decision logic. Because the ANSI APFs are adhered to in most modern workplaces, employers and end users would have to completely overhaul their existing respiratory protection programs to align with the NIOSH APF values. Then, when NIOSH releases its respirator certification module on APFs, employers and end users would have to go through this process all over again, at great expense and inconvenience and with little or no benefit to the wearer.

Rather than cause such unnecessary upheaval, therefore, OSHA should adopt the ANSI assigned protection factors as part of 29 CFR 1910.134. At the very least, OSHA should not require compliance with the outdated, incomplete, and faulty protection factors in the decision logic.

IX. Interagency Coordination

In early 1995, NIOSH is expected to release, in its final form, a thoroughly revised respirator certification rule for non-powered particulate respirators. This latest NIOSH revision represents the first in a series of modular rulemakings that are scheduled to occur over the next three years. NIOSH plans to release modules for assigned protection factors, administrative programs, quality assurance, other types of respirators and simulated workplace protection factor testing.

The revised NIOSH standard will include an entirely new scheme for respirator certification, which OSHA will need to coordinate with the requirements of its own standard. Each module could have a significant impact on the selection and use requirements of OSHA's respiratory protection standard. With the release of each successive NIOSH module, OSHA will have to revise its rule to blend the new certification criteria with its own requirements. In addition to air-purifying respirators, the requirements of each new module also may impact on the other types of respirators regulated by OSHA, including positive pressure self-contained breathing apparatus (SCBA), vapor- and gas-removing respirators and atmosphere-supplying airline respirators.

OSHA would do well to look at the current rulemaking pragmatically. Rather than viewing its efforts as a once in a decade rulemaking, OSHA should recognize that it will have number of opportunities to fine-tune 29 CFR 1910.134. The first chance will be for currently-approved NIOSH respirators and the second for those respirators certified under the new performance criteria. Each successive NIOSH module will present an opportunity for OSHA to retool the new standard.

In addition to the NIOSH proposal, the Mine Safety and Health Administration (MSHA) is in the process of revising its respiratory protection requirements. The OSHA proposal ties directly to NIOSH's certification standard and MSHA's respiratory protection rule. Therefore, as final publication of the proposed respiratory protection rule approaches, it is crucial that OSHA assert a leadership role among the various federal agencies charged with respirator regulation.

X. APFs and the NIOSH Respirator Users' Notice

In its pending certification rule, NIOSH proposes to reclassify particulate respirators as type A, B, and C, depending on the respirator's ability to filter a standard size challenge agent. This is quite different from the traditional hazard classification scheme of dust/fume, pesticide, and paint spray. NIOSH

has indicated that it will be issuing a Respirator Users' Notice simultaneous to publication of the final filter penetration module.

The Users' Notice will provide users with selection and use information so they can determine which respirators are appropriate for which hazardous exposures. This notice also will be used to cross-reference the new classes of respirators under 42 CFR 84 to particular workplace hazards (e.g., nuisance dusts, paints, pesticides, and substance-specific standards).

ISEA supports creating this document, and recommends that OSHA get directly involved in its development along with user groups, manufacturers representatives and other governmental agencies, such as MSHA and the Environmental Protection Agency.

XI. Industry Empowerment

The current OSHA respiratory protection program has not been modified in the 24 years since it was adopted. As a result, the standard is based on data that was generated over a quarter century ago. Respiratory protection theory and respirator technology have advanced significantly since publication of the original rule. OSHA's rulemaking process has not kept up with these advances, thereby depriving users of improved protection. In addition to devising a means of more easily incorporating advances in respirator technology, OSHA must enhance its ability to respond to such emerging hazards as TB in health-care settings.

In the face of increasing demands on internal resources and shrinking federal budgets, and in accordance with Vice President Gore's re-inventing government initiative, OSHA must find more efficient ways to implement its respiratory protection rule and subsequent compliance programs and enforcement efforts. A good example is NIOSH, which has developed a vision that would broaden the influence of their certification program without requiring significant additional resources. A major part of NIOSH's vision is industry empowerment.

ISEA recommends that OSHA adopt a similar objective of empowering industry. This would not only expand the resources and expertise available to the agency by creating partnerships with the private sector, it also would free federal funds to be applied directly to other projects designed to improve workplace health and safety.

ISEA urges OSHA to establish processes that encourage the creation of cooperative partnerships between the government and the private sector, taking advantage of the abundant private sector knowledge and resources to

help promote health and safety for the American worker. Areas where such cooperative arrangements could be formed include a policy of greater adherence to - and active participation in the development of - national consensus standards, and development of a standard peer review process to legitimize scientific studies conducted outside the agency.

XII. Economic Impact

Part of ISEA's concerns are economic. Over the years, ISEA has attempted to keep OSHA apprised of the basis and substance of these economic issues. In our March 29, 1994, submission to the docket, ISEA included an economic impact analysis based on a proposed reduction in the assigned protection factor for one type of continuous flow respirator. That analysis demonstrated that the cost to the abrasive blasting industry could be substantial if OSHA lowered the minimum protection factor that must be achieved for products to be approved for use in this industry. Similar economic effects would be felt throughout industries using other types of respirators if OSHA made similar reductions in APFs for other classes, thereby compounding the total impact of such a step.

As the study of the abrasive blasting industry demonstrates, the effects of changes in the respiratory protection rule could be significant. The various factors affecting the respirator users cited in the study may cause them to react strongly even to a proposed OSHA standard, much less to actual changes in the rule.

As mentioned earlier, much of the respiratory protection community already follows the requirements of ANSI Z88.2-1992. A radically revised respiratory protection standard would create disruption and confusion. If OSHA introduces significant new requirements in its final respiratory protection standard that are not necessary to provide adequate respiratory protection, the reaction of users and the accompanying negative economic impact on respirator manufacturers could be severe. This, in turn, would have a significant economic impact on both users and manufacturers. ISEA urges the agency, therefore, to avoid the economic harm to manufacturers and users that could result from a radically different OSHA standard.

XIII. Specific Issues Regarding 29 CFR 1910.134 as Proposed

(The italicized headings that follow correspond with the headings in the preamble and the text of OSHA's proposed respiratory protection rule.)

II. Introduction

C. Respirator Use

1) Issue: In the preamble to the proposed respiratory protection rule, OSHA states that for supplied air respirators, "compressed air from a stationary source is supplied through a high pressure hose connected to the respirator." (59 FR 58885)
Comment: ISEA recommends that the modifier "high pressure" be deleted from the statement that "compressed air from a stationary source is supplied through a high pressure hose connected to the respirator."

Rationale: "High pressure hose" is a term of art in the field of respiratory protection. For respiratory protection equipment, the standard pressure of 125 PSI is not considered high pressure. As a result, the statement in the preamble could create confusion for end users and others.

2) Issue: In the preamble to the proposed respiratory protection rule, OSHA refers to particulate PAPRs but not gas/vapor PAPRs. (59 FR 58885)

Comment: ISEA recommends that OSHA refer to both particulate and gas/vapor PAPRs.

Rationale: The current state of the art in powered air-purifying respirators has been achieved in both particulate and gas/vapor model PAPRs. Any standard that applies to PAPRs, therefore, should regulate both types.

E. Limitations of Respirator Use

3) Issue: In the preamble to the proposed respiratory protection rule, OSHA states that "[i]n principle, respirators frequently may be capable of providing adequate protection. However, problems associated with selection, fit, and use often render them ineffective in actual application, preventing the assurance of consistent and reliable protection." (59 FR 58885)

Comment: ISEA objects to the way in which the possibility of the inadequate respiratory protection is stated. ISEA recommends that the cited language be replaced with the following:

> "In principle, respirators *provide adequate protection.* However, problems associated with selection, fit, and use *can* render them ineffective in actual application, preventing the assurance of consistent and reliable protection." (suggested changes in italics)

Rationale: Although respiratory protection can be compromised as a result of improper selection, fit, and use, ISEA asserts that it is inappropriate and unfounded to state that this is "often" the case. OSHA offers no data to support its characterization. In addition, the preamble language stating that "[i]n principle, respirators frequently may be capable of providing adequate protection" reflects the inherent skepticism and partiality at OSHA and implies that the agency is biased against respirators. The suggested language, ISEA asserts, more accurately states the facts about respirator capabilities and the possibility of inadequate respiratory protection, and does so without passing judgment on respirators' effectiveness.

IV. Background

B. Need for the Standard

4) Issue: In the preamble to the proposed respiratory protection rule, OSHA indicates that in considering options for developing a new standard, "[o]ne regulatory alternative . . . would have been to adopt the ANSI Z88.2-1980 standard, or to at least base the rulemaking largely on the latest ANSI standard as was done with the original OSHA standard. ANSI, however, was developing a revision of its 1980 standard, recently finalized as ANSI Z88.2-1992. OSHA has given this latest ANSI standard detailed consideration in preparing this proposal. An OSHA standard based entirely on the 1980 ANSI standard would have been obsolete as soon as published. OSHA has therefore made the decision to pursue a rulemaking based on existing data and the record generated thus far by responses to the ANPR and the prepublication draft. The proposed standard has included provisions of the 1980 and 1992 ANSI standards where justified by the record." (59 FR 58889)

Comment: ISEA recommends that OSHA incorporate the requirements of ANSI Z88.2-1992, rather than create an entirely new standard.

Rationale: ANSI Z88.2-1992 is widely recognized as the state of the art for feasible practices in the proper selection and use of respirators. It is the standard adhered to in most modern workplaces and its incorporation by OSHA would not only bring all workplaces up to the same high level of respiratory protection, it also would cause the least amount of disruption for end users and manufacturers alike, almost all of whom base their respective purchasing and research and development decisions on its requirements. (For further discussion of the need for OSHA to adopt the requirements of ANSI Z88.2-1992, see Sections IV, V, and VI above.)

5) Issue: In the preamble to the proposed respiratory protection rule, OSHA uses outdated respirator use citation data from 1972 to 1982 to justify certain revisions to its respirator use standard. (59 FR 58890)

Comment: ISEA recommends that OSHA use current data to justify revisions to its respirator use standard.

Rationale: While ISEA agrees that the standard is sorely in need of updating, using data more than 20 years old does not reflect accurately the state of the art of respiratory protection. Respiratory protection has made great advances in the last two decades. For example, fit testing of respirator users was uncommon twenty years ago, but today the majority of respirator users are fit tested.

ISEA objects to the outdated data used in the regulatory impact and regulatory flexibility analyses. The problems referenced in the preamble no longer apply to most modern respirators. The requirements of the current standard may present a risk to users, but the respirators being used do not. This point is omitted from the discussion of risk and needs to be clarified.

6) Issue: In the preamble to the proposed respiratory protection rule, OSHA indicates that it "has decided not to establish its own set of numbers but instead to defer to NIOSH in setting assigned protection factors for the various respirator classes. NIOSH will be developing assigned protection factors as part of its revised respirator certification standard, 42 CFR 84. Since NIOSH may not publish 42 CFR 84 before this OSHA respirator standard revision is finalized, OSHA will in the interim enforce the assigned protection factors listed in the [1987] NIOSH Respirator Decision Logic." (59 FR 58890)

Comment: ISEA recommends that OSHA adopt the assigned protection factors of ANSI Z88.2-1992, rather than the APFs in the 1987 NIOSH Respirator Decision Logic.

Rationale: Earlier versions of OSHA's proposed respiratory protection standard called for a reduction of current assigned protection factors for specific respirators. APFs essentially are a multiple of the concentration of airborne contaminants at which a respirator will function to reduce actual worker exposures to the PEL or lower.

ISEA asserts that OSHA has no scientific support for reducing the protection factors currently assigned to particular types of respirators. Earlier drafts of the proposed standard indicated that the agency intended to lower the APFs for disposable dust/mist respirators. Outdated scientific data were presented by

OSHA to justify these reductions; OSHA merely relied upon its opinion without citing credible workplace studies of realistic exposures and activities.

The data from the studies ISEA provided OSHA support the opposite view : that the APFs recommended in ANSI Z88.2-1992 for these respirators are justifiable and based on sound scientific research. Because they provide adequate protection against particulates, OSHA should not reduce the existing APFs for disposable dust/mist or any other currently certified respirators. (For further discussion of the inadequacies of the NIOSH Respirator Decision Logic and the need for OSHA to adopt the APFs in ANSI Z88.2-1992, see Sections IV, V, VI, and VII above.)

C. Recognition of the Need for a Standard by Other Groups

7) Issue: In the preamble to the proposed respiratory protection rule, OSHA states that "[o]ther countries also recognized the need for standards governing the use of respirators. Of particular note is the consensus standard recently developed by the Canadian Standards Association [CSA] (Z94.4-M1982)." (59 FR 58891)

Comment: ISEA recommends that OSHA cite the current version of Canadian Standards Association Standard Z94.4, which was revised in 1992.

Rationale: By referencing CSA Standard Z94.4-M1982 as an example of current thinking in respiratory protection equipment, OSHA demonstrates that it is either unfamiliar with the current state of thinking in the respirator community or that it failed to review its own standard adequately prior to publication as a proposed rule. The 1982 CSA standard was revised in 1992 to reflect the changes made that year to ANSI Z88.2 and to the Z88.2-1992 assigned protection factors in particular. This implies an incomplete review of the earlier draft, which has resulted in a proposed rule that contains many inaccuracies.

8) Issue: In explaining the need for an updated respiratory protection standard, OSHA repeatedly references ANSI Z88.2-1980. (59 FR 58891)

Comment: ISEA urges OSHA to incorporate the requirements of ANSI Z88.2-1992, rather than ANSI Z88.2-1980, in its final respiratory protection rule.

Rationale: The 1980 ANSI standard was revised and replaced in 1992. While OSHA claims that it considered the 1992 revision in its current proposal, its repeated references to the 1980 standard implies that it did not investigate

ANSI Z88.2-1992 adequately. (For further discussion of ANSI Z88.2-1992, see Sections IV, V and VI above.)

VII. Summary and Explanation of the Proposed Standard

(A) Scope and Application

9) Issue: In the preamble to the proposed respiratory protection rule, OSHA states "[i]f a respirator is used by an employee but its use is not required by OSHA standards or statute, or by the employer which is known as a voluntary respirator use situation, then the requirements of the proposed standard although recommended, are not proposed to be mandatory." (59 FR 58895)

Comment: ISEA recommends that in voluntary respirator use situations, adherence to the requirements of the proposed standard should be mandatory.

Rationale: Training is an essential aspect of proper respirator use, regardless of the reason or motivation for use and regardless of whether use is mandatory or voluntary. By making the training requirements of the proposed rule mandatory, OSHA would increase the chances for all respirator users to receive the maximum level of protection that respirators can provide.

10) Issue: In the preamble to the proposed respiratory protection rule, OSHA proposes "a threshold of five hours of respirator wear in any work week before a medical evaluation must be obtained." (59 FR 58896)

Comment: ISEA recommends that the rule not establish a minimum duration of respirator wear as a medical evaluation trigger.

Rationale: It is not logical to place any sort of time threshold on respirator use as a trigger for medical evaluation requirements. Different types of respirators and different uses would require different types of medical evaluations as different levels of stress would be placed on each individual who uses a respirator. For instance, an individual wearing a dust/mist respirator would experience considerably less stress than to someone performing emergency response wearing an SCBA. (For our specific comments on medical evaluations see ISEA Issue #21.)

In addition, even one minute or one hour in a hazardous environment might cause more damage than five hours in a less hazardous environment. Setting any time limit on triggering medical evaluations, therefore, would be inappropriate. The specifics of each situation should dictate the depth and

detail of the overall program, including any requirement for conducting medical evaluations.

If a threshold time must be established in the rule for purposes of application of the standard, ISEA suggests that any use at all should trigger the medical evaluation requirement in all but nuisance exposure situations.

(B) Definitions

11) Issue: In the preamble to the proposed respiratory protection rule, OSHA claims most of the definitions in the standard "are based on generally recognized sources, such as the current ANSI standard." (59 FR 58896)

Comment: ISEA disagrees with the statement that most definitions in the proposed rule "are based on generally recognized sources"; OSHA should incorporate the most recent ANSI definitions found in ANSI Z88.2-1992.

In addition, a number of key definitions are missing; e.g., respiratory inlet covering; loose fitting facepiece, tight-fitting, half and full facepiece, helmet and hood; fit check; respiratory hazards (dust, fume, mist, etc.).

ISEA provides specific comment on the following definitions:

- The word "chemical" in the definition for "adequate warning properties" should be replaced by "gas or vapor" to make it clear that warning properties are not a concern for particulates.

- The definition for "assigned protection factor" should be revised as follows: "The expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users."

- The term "air-supplied" should be changed to "supplied air" in the definition for "atmosphere supplying respirator" to be consistent with 30 CFR 11 and OSHA's own SAR definition included in this proposed revision.

- The definition for "disposable respirator" should be expanded to address maintenance and repair issues as follows: "a respiratory protective device which cannot be re-supplied with an unused filter or cartridge, is not intended to be maintained or repaired, and which is to be discarded in its entirety after its useful service life has been reached."

- The definition of "fit factor" should revised as follows: "a quantitative measure of the fit of a particular respirator to a particular individual." The current definition restricts currently approved products and limits innovation.

- The reference to TLVs in the definition of "hazardous exposure level" should include the latest edition. Otherwise, OSHA is in violation of the Administrative Procedures Act by not specifying an edition, thus giving the ACGIH legislative authority through open-ended approval of future editions.

- The OSHA proposed term "hazardous exposure level" should replace "permissible exposure limit" in the definition for "maximum use concentration."

- The term "oxygen deficient atmosphere" should be changed to "oxygen deficient atmosphere - not IDLH" for clarity.

- The definition for "positive pressure respirator" excludes PAPRs as well as hoods, helmets and loose-fitting facepieces. The following definition is recommended: "a respirator in which the pressure inside the respiratory inlet covering is normally positive with respect to the ambient air pressure. This includes powered air-purifying, pressure demand, and continuous flow respirators."

- The definition for "pressure demand" should read: "a positive pressure atmosphere-supplying respirator that admits respirable gases to the facepiece when the positive pressure is reduced inside the facepiece by inhalation." The pressure within a positive pressure facepiece cycles during respiration.

- The proposed definition for "quantitative fit test (QNFT)" is based on existing technology and restricts innovation. ISEA recommends the following: "A fit test which measures the challenge agent inside and outside the respirator."

- The term "intended" should be replaced by "designed" in the definition for "respirator." Use of the word "intended" is vague. Anyone, including the manufacturer, employer, and the wearer, could be the source for making a decision as to the type of protection intended.

- The definition for "service life" of a chemical or organic vapor cartridge or canister is unclear since breakthrough, humidity, and other test conditions are not specified. It appears that manufacturers are required to run breakthrough studies for each possible contaminant. Manufacturers should be responsible for substances in the NIOSH certification. Also, it would not

recognize any other source of cartridge/canister data other than the manufacturer. ISEA recommends the following definition: "service life - the period of time that a respirator provides adequate protection to the wearer."

Rationale: More definitions should be included to provide better understanding to the end user. The ANSI Z88.2-1992 standard represents the most recent knowledge on respiratory protection and was developed by a broad range of respiratory experts. (See section VI for further discussion.)

12) Issue: In the preamble to the proposed respiratory protection rule, OSHA indicates that Immediately Dangerous to Life or Health (IDLH) means "an atmospheric concentration of any toxic, corrosive, or asphyxiant substance that poses an immediate threat to life or would cause irreversible or delayed adverse health affects or would interfere with an individual's ability to escape from a dangerous atmosphere." (59 FR 58897)

Comment: ISEA recommends the adoption of the definition of IDLH from ANSI Z88.2-1992, which defines as Immediately Dangerous to Life or Health "[a]ny atmosphere that poses an immediate hazard to life or poses immediate irreversible debilitating effects on health."

Rationale: The ANSI definition is more focused and makes more sense in terms of the true meaning of IDLH, which is intended to stress the immediacy of the hazard. To include "or delayed adverse health effects" in the definition is too broad as many chemicals can have a delayed health effect while posing no immediate hazard.

(D) Selection of Respirators

1. Introduction

13) Issue: In the preamble to the proposed respiratory protection rule, OSHA indicates that "[w]here elastomeric facepieces are to be used, the employer shall provide a selection of respirators from an assortment of at least three sizes for each type of facepiece from at least two manufacturers." (59 FR 58900)

Comment: ISEA recommends that OSHA adopt the performance language from ANSI Z88.2-1992, which requires that "an appropriate number of sizes and models shall be available from which a satisfactory respirator can be selected," rather than the requirement of "an assortment of at least three sizes for each type of facepiece from at least two manufacturers" in the proposed rule.

Rationale: The proposed OSHA requirement of "an assortment of at least three sizes for each type of facepiece from at least two manufacturers," is overly burdensome. It forces employers to provide more options than may be necessary, especially for small workforces, and adds an expense that does not necessarily provide any measurable benefit to the end user. In many situations, only one respirator will need to be selected and tested for each individual wearer.

ISEA agrees that employers who have a large number of respirator wearers need to offer their workers a wider variety of respirators to maximize their employees' chances of obtaining the best fitting respirator available. If only a few wearers are present in a workplace, however, one model and size might suffice. In addition, many manufacturers make more than one style of facepiece to better fulfill the needs of the wearer.

Employers, therefore, should be given some leeway in determining what respirator options they make available to their employees. ISEA is not suggesting that employers be relieved of responsibility for making available a sufficient number of options for their employees, but ISEA does recommend that OSHA not force employers to provide more options than are necessary to provide adequate protection.

Section 9.3.1 of the ANSI standard requires that "an appropriate number of sizes and models shall be available from which a satisfactory respirator can be selected. The number of models and sizes necessary to fulfill the intent of this requirements will vary for workplaces. For example, in a workplace with four workers, one model and size may fulfill the requirement; whereas a workplace with a hundred different wearers may require different models in various sizes." This language allows employers some discretion in what options they provide to employees without relieving them of an obligation to present an adequate selection of models and sizes.

3. Use of NIOSH/MSHA Certified Respirators

14) Issue: In the preamble to the proposed respiratory protection rule, OSHA adopts the assigned protection factors from the 1987 NIOSH Respirator Decision Logic. (59 FR 58901)

Comment: ISEA recommends that OSHA either (i) adopt the ANSI Z88.2-1992 assigned protection factors until NIOSH issues its module for assigned protection factors or (ii) delay issuance of its final rule until after the NIOSH assigned protection factor module is published.

Rationale: (For a discussion of the inadequacies of the NIOSH Respirator Decision Logic and the need for OSHA to adopt the APFs in ANSI Z88.2-1992, see Sections IV, V and VI above and ISEA Issue #6.)

15) Issue: In the preamble to the proposed respiratory protection rule, OSHA invites comment on "whether to require NIOSH approval for the respirators selected, and on alternatives to this requirement, including practical considerations of compliance and enforcement." (59 FR 58901)

Comment: ISEA asserts that, when available, NIOSH-certified respirators should be required for users seeking to achieve compliance with 29 CFR 1910.134.

Rationale: To be NIOSH-certified, respirators must meet stringent manufacturing and quality controls, which will help ensure that respirators are capable of providing adequate respiratory protection. By mandating that all respiratory protection programs subject to the proposed OSHA rule must use NIOSH-certified respirators, OSHA is promoting uniformity in the protection that respiratory protection programs can provide. This will enhance the ability of employers to comply with the rule and will ease OSHA inspectors' efforts to ascertain compliance with the new regulation by providing them with consistent minimum criteria to use during inspections.

16) Issue: In the preamble to the proposed respiratory protection rule, OSHA states that "[w]hile it is true that OSHA has in the past approved the use of certain unapproved respirators, this approval has generally been as the result of a thorough review of the respirators' capabilities as part of a substance-specific standard. OSHA does not have the personnel or facilities to perform respirator testing, and has no present plans to set itself up as a respirator approval agency. Therefore, this proposed respirator standard does not contain language which would formalize a procedure for approving respirators. OSHA invites comment on whether and how such an approval procedure should be added to the standard." (59 FR 58901)

Comment: ISEA recommends that, in cases where NIOSH approval does not exist for a certain type of respirator that is to be used in a particular type of environment (e.g., supplied air suits to be used in a very hot environment), OSHA should be able to approve the use of such products on a case-by-case basis.

Rationale: The agency should retain the option of approving uses for respirators that are not covered in the general provisions of either the NIOSH

respirator certification standard or the proposed respiratory protection rule. This would enable an employer to obtain an exemption from specific requirements in the rule if the rule does not address a particular situation with which an employer is confronted.

4. Assigned Protection Factors

17) Issue: In the preamble to the proposed respiratory protection rule, OSHA states that "it is not sufficient for OSHA to reference the ANSI recommended protection factors because ANSI has provided no discussion of the basis for its recommendations . . . Only if ANSI were to supply detailed discussion as to how its protection factors were derived - including reference to and complete description of specific studies used to derive those APFs - would OSHA be able to evaluate the merits of the latest ANSI recommendations." (59 FR 58902)

Comment: ISEA asserts that, despite OSHA's claims to the contrary, there is adequate scientific support for the assigned protection factors in ANSI Z88.2-1992 and these APFs should be adopted in the OSHA rule, rather than the APFs in the 1987 NIOSH Respirator Decision Logic, for which no scientific rationale is offered.

Rationale: The ANSI comments are well supported by scientific studies and data. All of these studies have been submitted to OSHA by ISEA, yet the agency continues to assert that the ANSI assigned protection factors are not supported by science. (For further discussion of the respective merits of the ANSI and NIOSH assigned protection factors see: Sections IV, V, VI, and VII above; "The Assigned Protection Factor According to ANSI" by T. J. Nelson (see ISEA Attachment # 1); and the workplace protection factor studies supporting the ANSI values that ISEA submitted to the respiratory protection rulemaking docket (Docket H-049, Exhibit # 51).)

18) Issue: In the preamble to the proposed respiratory protection rule, OSHA states that "[w]hen NIOSH completes its rulemaking process of assigned protection factors, OSHA will issue a technical amendment to this respiratory protection standard referring to the NIOSH final regulation. OSHA does not intend to have notice and comment on its technical amendments because NIOSH will have notice and comment in its rulemaking." (59 FR 58903)

Comment: ISEA recommends that all technical amendments to the OSHA standard go through standard notice and comment procedures as part of this rulemaking, as should all compliance directives and other binding documents released by the agency.

Rationale: Were OSHA to make technical amendments to its own standard without a period of notice and comment, even when incorporating a NIOSH provision that already has undergone that agency's notice and comment process, it would constitute an attempt by OSHA at de facto rulemaking. So that all parties will support the requirements and validity of OSHA's respiratory protection rule, OSHA should subject technical amendments to the process of notice and comment.

5. Warning Properties

19) Issue: In the preamble to the proposed respiratory protection rule, OSHA proposes that "the use of air-purifying respirators in the absence of adequate warning properties be restricted to situations where the odor, taste, or irritation threshold is not more than three times the hazardous exposure level." (59 FR 58904)

Comment: ISEA recommends that, in situations that lack adequate warning properties, OSHA adopt Section 7.2.2.2(m) of ANSI Z88.2-1992, which permits the use of air-purifying respirators against hazards with inadequate warning properties only if the respirator has an end of service life indicator or the user implements an appropriate cartridge change schedule.

Rationale: Safe exposure levels for hazardous gas and vapors continue to drop, which increases the percentage of contaminants that lack adequate warning properties. In addition, warning properties can vary more than an order of magnitude from person to person. Unlike what OSHA proposes, the ANSI standard does not contain the "not more than three times the hazardous exposure level" restriction if appropriate cartridge change schedules are implemented.

The cartridge change schedule recommended in Section 7.2.2.2(m) of ANSI Z88.2-1992, which includes an appropriate safety margin (greater than the 80% recommended by OSHA), would provide more safety to the user than reliance on the adequate warning properties of a particular gas or vapor.

6. Oxygen Deficient and Oxygen Deficient IDLH Atmospheres

20) Issue: In the preamble to the proposed respiratory protection rule, OSHA states that "[t]he safety margins in the ANSI Z88.2-1992 oxygen deficiency IDLH and non IDLH definitions have been reduced to their bare minimums. OSHA has chosen to reject these less protective ANSI oxygen deficiency

definitions in favor of the more forgiving levels it is proposing to adopt." (59 FR 58906)

Comment: ISEA recommends that OSHA adopt the ANSI Z88.2-1992 procedures for dealing with oxygen-deficient atmospheres.

Rationale: ISEA does not agree that margins of safety should be built into IDLH levels. Instead, the IDLH level should in fact be "immediately dangerous." If a margin of safety is built into the IDLH level, the level may not be taken as seriously. Such a built-in buffer could be taken advantage of, which would negate any benefit of adding a safety factor.

(E) Medical Evaluations

21) Issue: In the proposed respiratory protection rule, OSHA "requires that a written opinion be obtained from a physician that each employee who needs to wear a respirator for five hours or more during any work week is fit to wear one." (59 FR 58907)

Comment: ISEA recommends that there not be a minimum period of exposure that triggers the need for a medical examination.

Rationale: The five-hour requirement sets an arbitrary time limit. A wearer could be exposed to an extremely hazardous environment every week for less than five hours each week, yet not be required to submit to a medical evaluation. A more appropriate question is whether an employee that consistently uses a respirator for less than five hours a week could still compromise their health by not submitting to a medical evaluation.

Time of potential exposure is the wrong criterion. OSHA must look instead to the potential hazards of the environment from which a wearer must be protected. Any wearer subjected to a hazardous environment, regardless of duration, should be required to submit to at least a basic medical evaluation.

22) Issue: In the preamble to the proposed respiratory protection rule, OSHA invites comment on three alternative medical evaluations to ascertain fitness to wear a respirator. In the preamble, OSHA states "[t]he first . . . would require that the employer obtain a doctor's written opinion on the employee's ability to wear a respirator. The nature of the medical evaluation performed would be left up to the physician to determine. The second alternative would require the performing of a medical evaluation consisting of a medical history and medical examination, from which a physician's opinion on respirator use would be

written. The third alternative would require that a health questionnaire be administered to all respirator wearers, with a medical evaluation being performed on those whose answers to any of the questions on the questionnaire show the need for such evaluation, or who wear an SCBA for emergency or rescue operations. After reviewing the questionnaires and any medical evaluation performed, a physician's written opinion on respirator use would then be prepared." (59 FR 58907)

Comment: ISEA encourages OSHA to adopt alternative number three, which requires that a health questionnaire be administered to all respirator wearers, and a medical evaluation be performed on those whose answers to any of the questions on the questionnaire show the need for such evaluation, or who wear an SCBA for emergency or rescue operations. After reviewing the questionnaires and any medical evaluation performed, a physician's written opinion on respirator use would then be prepared.

Rationale: ISEA agrees that this method would provide the most cost-effective and complete answer to the question regarding medical evaluations of fitness to wear a respirator. In many cases a full medical examination is not necessary.

If the duties of each job at a worksite where respirators are needed are clearly delineated, worksite concentrations documented, length of time of exposure and any other pertinent information assembled, an occupational physician could, in conjunction with a certified industrial hygienist and the employer, develop a program based on these factors. The program would require administration of a questionnaire asking personal medical information that may indicate the need for an in-depth medical examination. ISEA urges that employers assisted by industrial hygienists and occupational medicine physicians be given the latitude to decide the extent of medical evaluation needed, based on the facts in each situation.

In the experience of ISEA member companies, respirators (other than SCBAs) do not add a significant physical burden to a wearer performing a task. If a person is physically capable of performing a job without a respirator, they should be able to safely perform the same function with a respirator. ISEA opposes as unnecessary any medical examination by a physician unless the results of the questionnaire proposed in medical evaluation alternative three indicated the existence of some unusual condition.

For SCBA use, especially in emergency response situations, a preliminary medical examination would be warranted because of the stress that the wearer would undergo.

23) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on the need to assess the ability to hear when wearing a respirator and on the appropriateness of including this requirement in the respiratory protection standard. (59 FR 58908)

Comment: ISEA opposes as unnecessary and inappropriate any requirement to assess hearing ability any further than is proposed in non-mandatory Appendix C, which applies to all three medical evaluation alternatives.

Rationale: This subject should be addressed in the general job requirements set forth by the employer. It is the employer's responsibility to evaluate their worksite for hazards, including hazards associated with the need to wear proper hearing protection and the need to hear well. This applies to any situation, including those where respirators do not need to be worn.

24) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on the requirement to assess the condition of a wearer's endocrine system and to determine which endocrine system conditions would preclude the use of respirators. (59 FR 58909)

Comment: ISEA opposes as inappropriate any requirement to assess a wearer's endocrine system or to identify dangerous endocrine conditions in the respiratory protection standard.

Rationale: This subject should be addressed by the general job requirements set forth by the employer. It is the employer's responsibility to evaluate its worksite for all hazards, including the possibility of someone losing consciousness. It is impossible, however, to predict every eventuality in the workplace.

25) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on which provisions should be retained as part of non-mandatory Appendix C, and whether certain provisions such as those requiring testing of pulmonary functions or exercise stress should remain in the appendix or be made mandatory provisions of the standard. OSHA also seeks additional comment on whether it should add a section to the non-mandatory appendix further describing health conditions that should be considered during the medical evaluation. (59 FR 58909)

Comment: ISEA suggests that any information that is pertinent to a wearer's medical condition and ability to use a respirator should be included in the non-mandatory appendix.

Rationale: This information should be used and evaluated on a case-by-base basis and should not be mandatory in all situations.

26) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on whether the rule should include a requirement for an annual review of each employee's medical status, or if a sliding scale of examination dates (as recommended by NIOSH and ANSI) could substitute for an annual medical review. (59 FR 58910)

Comment: ISEA supports the concept of a sliding scale of medical examinations if medical evaluations are made a mandatory condition of the respiratory protection rule.

Rationale: As observed in ISEA Issue #22 above, ISEA considers a medical examination by a physician unnecessary unless the results of the questionnaire proposed in medical evaluation alternative three indicated the existence of some unusual condition. If a medical evaluation was required, however, a sliding scale based on the physiological stress of the work environment and the type of respiratory protection used would be more appropriate in many cases than an annual review. A sliding scale would give employers more flexibility and would account for differences among workplaces. A mandatory annual review, on the other hand, is too rigid.

27) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on the requirement that all medical evaluations be performed by a licensed physician and on the proper role for these health professionals to play. (59 FR 58910)

Comment: As observed in ISEA Issue #22 above, ISEA considers a medical examination by a physician unnecessary unless the results of the questionnaire proposed in medical evaluation alternative three indicated the existence of some unusual condition. If a medical examination is required, however, ISEA urges OSHA to allow health professionals to perform parts of the examination.

Rationale: If a health professional performs their duties under the supervision of a licensed practitioner, ISEA sees no reason to preclude these health professionals from performing some of those duties. Health professionals usually are licensed and very well trained. As an example, when an individual goes for a routine check-up, it is rare that a doctor will perform the entire

examination. In some cases, the health professional may be more adept in performing certain duties than a doctor.

28) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on "whether the medical evaluation provisions should be less extensive for less burdensome respirators, such as positive pressure respirators, or single use dust masks, and, if not, what provisions could be reduced or eliminated. More generally, comment is sought on whether the medical evaluation provisions should be modified to accommodate particular respirator work conditions, and, if so, what those modifications should be." (59 FR 58910)

Comment: As observed in ISEA Issue #22 above, ISEA considers a medical examination by a physician unnecessary unless the results of the questionnaire proposed in medical evaluation alternative three indicated the existence of some unusual condition. If a medical evaluation is required, however, its extent should be a function of workplace conditions, physiological stress, hazard, type of respiratory protection used, and any other relevant concerns.

29) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on the propriety of administering a medical questionnaire and on who should administer such a questionnaire. (59 FR 58911)

Comment: As observed in ISEA Issue #22 above, ISEA considers a medical examination by a physician unnecessary unless the results of the questionnaire proposed in medical evaluation alternative three indicated the existence of some unusual condition. If a medical evaluation is required, ISEA recommends that a questionnaire be used as the most appropriate means of performing an initial medical evaluation.

Rationale: Adequate medical questionnaires can be developed through cooperative efforts among the employer, an industrial hygienist and a physician. Questionnaires can be developed for each employer's need with consideration given to factors such as type of worksite condition, exposure to contaminants, physiological and ergonomic considerations, and any other pertinent factors. They then could be administered by a person who has been assigned the responsibility of administering the medical part of the respirator program, provided it is with a physician's input and consultation.

30) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on the need to perform a medical examination for SCBA wearers assigned to emergency or rescue operations, and on appropriate medical procedures to be used to evaluate their ability to perform adequately during such emergency or rescue operations. (59 FR 58911)

Comment: As observed in ISEA Issue #22, ISEA considers a medical examination by a physician unnecessary unless the results of the questionnaire proposed in medical evaluation alternative three indicated the existence of some unusual condition. If a medical evaluation is required, ISEA asserts that the physiological stress posed by the use of SCBA equipment and emergency or rescue situations would warrant a more in-depth medical evaluation than that needed for lower forms of protection or less urgent use situations.

Rationale: As stated earlier, the depth of the medical evaluation should be in accordance with the use situation and any ancillary factors.

31) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on appropriate requirements in situations where an employee is found to be unable to wear a negative pressure respirator for medical reasons. (59 FR 58912, 58934)

Comment: ISEA recommends that when an employee is found to be unable to wear a negative pressure respirator for medical reasons, OSHA should require employers to ensure that all types of currently available respirators, including PAPRs and supplied air respirators, have been considered and made available as possible alternative sources of respiratory protection.

Rationale: Many models of PAPRs and supplied air respirators allow the wearer to achieve the same or higher levels of respiratory protection as could be obtained when using a negative pressure respirator. They can also offer such advantages as decreased breathing resistance and reduced skin contact. The continuous flow of air over the head and face also may increase the wearer's comfort and resistance to fatigue in hostile environments. Where medical factors render an employee unable to wear a negative pressure respirator, employers should be required to provide reasonable alternatives.

32) Issue: In section (e)(1) of the proposed respiratory protection rule, OSHA proposes that for "each employee required to wear a respirator for more than five hours during any work week, the employer shall obtain from a licensed physician a written opinion which states whether the employee has any

detected medical condition which would place the employee's health at increased risk limitations upon the use of respirators." (59 FR 58940)

Comment: ISEA recommends that OSHA adopt medical evaluation alternative three as laid out in the preamble.

Rationale: One minute or one hour in a hazardous environment could cause much more damage than five hours in a less hazardous environment. The situation should dictate the depth and detail of the overall program, including any required medical evaluations. If required to suggest a minimum time threshold to trigger medical evaluations, ISEA would recommend that any use of a respirator should trigger a medical evaluation in all but nuisance exposure conditions.

In many cases, a full medical examination is not necessary. If the duties of jobs at a worksite where respirators are needed are clearly delineated, worksite concentrations are documented, and length of time of exposure and any other pertinent information are assembled, an occupational physician in conjunction with a certified industrial hygienist and the employer could develop a program based on these factors. The proposal requires employees to respond to a questionnaire that asks for personal medical information and may require an in-depth medical examination. ISEA recommends that employers - with the assistance of an industrial hygienist and an occupational medicine physician - should be given the latitude to decide the extent of medical evaluation, based on the particulars of each situation. It is not warranted in many cases to require a medical examination for certain situations.

33) Issue: In section (e)(3) of the proposed respiratory protection rule, OSHA proposes that an employer "shall have the employee's medical status reviewed by, or under the supervision of, a licensed physician annually and at any time the employee experiences unusual difficulty breathing while being fitted for or while using a respirator." (59 FR 58940)

Comment: As observed in ISEA Issue #22, ISEA considers a medical examination by a physician unnecessary unless the results of the questionnaire proposed in medical evaluation alternative three indicate the existence of some unusual condition. If a medical evaluation is required, ISEA recommends that any review of medical status be on a sliding scale and be incorporated into medical evaluation alternative three, as suggested in the preamble.

Rationale: The sliding scale should be based on the physiological stress of the work environment and the type of respiratory protection used. In any situation

in which an employee has unusual difficulty breathing while wearing a respirator, this should trigger a medical evaluation.

(F) Fit Testing Procedures

34) Issue: In the preamble to the proposed respiratory protection rule, OSHA invites interested parties to submit data showing how well a qualitative fit test (QLFT) protocol can detect full facepiece respirators that do not fit well. (59 FR 58913)

Comment: ISEA recommends that OSHA allow the use of the isoamyl acetate QLFT for full facepiece respirators if the test concentration is raised to ten times the concentration used for half masks.

Rationale: ISEA member companies have validated an isoamyl acetate qualitative fit test that can be used to detect poor-fitting full facepiece respirators. The data and statistical analysis supporting this fit test is included as ISEA Attachment # 2. The protocol used for the test was essentially the same as the isoamyl acetate test found in OSHA's lead standard, except that the concentration was raised to ten times that used in the lead standard. The anticipated pass/fail cutoff was determined to be a fit factor of 1000, which is consistent with an assigned protection factor of 100. The results of this QLFT meet the requirements of the September 17, 1989, draft of ANSI Standard Z88.10, *Respirator Fit Methods*[1], as well as the proposed OSHA requirements.

35) Issue: In the preamble to the proposed respiratory protection rule, OSHA states that "[t]he proposal requires fit testing of tight fitting atmosphere-supplying and powered air-purifying respirators." (59 FR 58913)

Comment: ISEA supports the extension of fit testing to tight-fitting, positive pressure systems.

Rationale: This recommendation also is in line with the recommendations in ANSI Z88.2-1992.

36) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on suitable validation procedures for new fit tests and seeks to identify organizations that can be designated credible validation performers. In the absence of performance-oriented criteria for assessing fit test reliability,

[1] See attachment #4, September 17, 1989, draft of ANSI Standard Z88.10

OSHA proposes allowing the use of qualitative or quantitative fit tests other than those specified in Appendix A, provided they are validated as providing equivalent or better reliability than those in the appendix. (59 FR 58913)

Comment: ISEA urges OSHA to adopt the fit test validation procedures in the September 17, 1989, draft of ANSI Standard Z88.10[1] and to permit any technical organization that generates adequate, scientifically valid data to recommend to the agency alternative fit tests that they have validated.

Rationale: The Z88.10[1] requirements do not differ significantly from the validation requirements found in the proposed appendix. To better coordinate the requirements of the rest of the rule (which should incorporate the provisions of ANSI Z88.2-1992), the validation criteria in the respiratory protection rule should follow ANSI Z88.10[1].

In support of efforts by the government to empower private industry, organizations with sufficient technical capability should be allowed to perform independent fit test validations. Limiting the data accepted by OSHA to that produced by specific types of organizations may discourage other organizations possessing significant resources from developing alternative methods of fit testing.

The use of a qualitative fit test should not necessarily be limited to products assigned a protection factor of ten if the qualitative fit test has been properly validated for those products and can be shown to be valid for products assigned protection factors higher than ten.

37) Issue: In the preamble to the proposed respiratory protection rule, OSHA states that "[i]f an employer chooses to use quantitative fit testing, a full facepiece respirator may be used up to a maximum of its [APF] of 50 . . . provided that the fit factor obtained during quantitative fit testing is at least 500." (59 FR 58913)

Comment: ISEA recommends that where a fit factor obtained during quantitative fit testing is at least 1000, a full facepiece respirator should be granted a maximum APF of 100, in accordance with ANSI Z88.2-1992.

Rationale: See the discussion in Sections IV, V, and VI in support of the assigned protection factors in ANSI Z88.2-1992.

38) Issue: In the preamble and Appendix A to the proposed respiratory protection rule, OSHA does not include use of the TSI Portacount machine as an acceptable quantitative fit test. (59 FR 58914)

Comment: ISEA recommends that the TSI Portacount and other validated fit test methods be included in the respiratory protection rule.

Rationale: The vast majority of users performing quantitative fit tests (QNFTs) today are using the Portacount machine and many published reports attest to its effectiveness. The TSI Portacount fit testing machine, however, is referenced only briefly by OSHA in its summary discussion of the contents of Appendix A. Although the Portacount is the quantitative fit testing technology most commonly used today, it is not included as an established quantitative fit test protocol.

As the Portacount protocol has long been available to OSHA for validation, it is odd that the agency has not included it in Appendix A. This omission is even more curious in light of two internal agency memoranda, dated October 21, 1993, and June 24, 1994, stating the agency's policy that use of the Portacount and one other type of quantitative fit testing technology were to be viewed by inspectors as de minimis violations of agency standards that require quantitative fit testing. (Copies of these memoranda are included as ISEA Attachment # 3.)

39) Issue: In the preamble to the proposed respiratory protection rule, OSHA invites comment on the requirement of annual fit testing and on alternate fit testing frequencies. The agency also proposes that, where APFs higher than ten are required (requiring quantitative fit testing), an employer may use a qualitative fit test to select respirators for new employees, provided that a quantitative fit test is administered within 30 days. (59 FR 58914)

Comment: ISEA agrees that fit testing should be performed on an annual basis, at a minimum, and should be coupled with retraining. ISEA supports the exception allowing use of a QLFT to select respirators for new employees is valid in situations where a QNFT is required as long as a QNFT is performed within 30 days. ISEA urges OSHA to broaden the exception to allow QLFT tests - under the same restrictions - in situations where QNFT testing cannot be conducted immediately.

Rationale: Fit testing is an important way to ensure that a tight fitting respirator fits the wearer properly. It is not only appropriate but incumbent upon the employer to ensure proper fit at least annually, and possibly more if the situation warrants.

Qualitative fit testing is validated with a safety factor of 10. As a result, when a respirator is assigned a protection factor of 10 based on a QLFT fit test, it

actually has achieved a fit factor of 100. In cases where the employer cannot immediately perform a QNFT, a QLFT should be allowed. Not allowing a QLFT could create undue hardship to the employer and serves no purpose if the employer is using sound judgment with respect to the respiratory protection assigned for a particular worksite. If the employer has used good judgment, he should have already incorporated a reasonable safety factor in choosing the appropriate respirator for a particular worksite.

Permitting qualitative fit testing in situations where quantitative fit testing cannot be conducted immediately would allow the employer some latitude in situations where their employees need to wear respirators but immediate quantitative fit testing is not possible. The requirement that a quantitative fit test be conducted within 30 days ensures that the necessary protection will be provided to the wearer.

40) Issue: In the preamble to the proposed respiratory protection rule, OSHA asks whether new qualitative fit tests should be required to meet the same criteria as the currently established qualitative fit test or whether it should establish minimum criteria requiring that the tests detect 95 percent of the poor fitting respirators with 95 percent confidence. (59 FR 58915)

Comment: ISEA recommends that any new qualitative fit tests should perform at least as well as the current QLFT, but OSHA should not establish more stringent requirements.

Rationale: Based on the workplace testing that has been performed using the established qualitative fit tests, the current performance levels are adequate. Respirators passing established qualitative fit tests consistently demonstrate workplace protection factors in excess of their assigned protection factors.

41) Issue: In the preamble to the proposed respiratory protection rule, OSHA invites comment on whether the particle size of qualitative fit test agents should be specified. (59 FR 58915)

Comment: ISEA recommends that the particle size of the qualitative fit test agent not be specified.

Rationale: All of the new fit tests will be validated. If the particle size of the fit test agent is inappropriate, the new fit test will not be validated. This standard should not be based on theoretical considerations as that could hinder innovation.

42) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on how new technology for fit testing should be approved, and what ground rules for minimum criteria OSHA should establish concerning its use. (59 FR 58915)

Comment: See Comment and Rationale for ISEA Comments #36 and #40 above.

43) Issue: In the proposed respiratory protection rule, OSHA has changed the exercises required in both the qualitative and quantitative fit test protocol. (59 FR 58916)

Comment: ISEA recommends that OSHA remove the grimace from all QLFT and QNFT protocols.

Rationale: The grimace exercise is intended to break the seal of the respirator and assess its ability to reseal once grimacing has stopped. Leakage during the exercise is not considered a failure. The addition of this exercise, however, is likely to reduce the accuracy of both qualitative and quantitative fit tests.

The test subject's sense of smell will be overwhelmed in the isoamyl acetate test, their sense of taste will be overwhelmed in the saccharin test, and they will be subject to extreme and perhaps hazardous irritation levels with the irritant smoke test. The addition of this exercise has been done without any experimentation or validation and it should be removed because of its ability to reduce the efficacy of qualitative fit tests.

In the QNFT situation, any leakage that occurs during the grimace exercise would be indistinguishable from overall filter leakage. No accurate measurement could be taken and the validity of the QNFT also would be compromised.

44) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on whether a record of each fit test should be retained or if employers should be allowed to certify that their employees have been fit tested. (59 FR 58916)

Comment: ISEA recommends that employers be required to retain a record of all training provided to each employee and be allowed to certify that fit testing was a part of that training.

Rationale: Since fit testing should be a part of all employees' training, one record should suffice.

45) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on the appropriate means for users to assure that their QNFT equipment is functioning properly. (59 FR 58917)

Comment: ISEA recommends that users be required to follow the manufacturers' instructions for maintenance and calibration of quantitative fit test equipment.

Rationale: Because of the complexity of the equipment, the user should not be required to perform any maintenance or calibration beyond what is recommended in the manufacturer's instructions.

46) Issue: In the preamble to the proposed respiratory protection rule, OSHA requires that "to successfully complete a QNFT the test subject must complete three separate tests with the same respirator. . . with the lowest fit factor obtained being used to determine whether the minimum required fit factor is exceeded." (59 FR 58920)

Comment: ISEA suggests that one quantitative fit test is sufficient to determine whether the minimum required fit factor is obtained.

Rationale: Since a respirator user can rely on either a quantitative or qualitative fit test, it makes little sense to require three QNFTs but only one QLFT. Very little additional statistical confidence is gained by taking the lowest value of three QNFT tests instead of one QLFT test, since both tests are conducted to assure proper fit.

Requiring three QNFT fit tests also is unnecessary because existing QNFT requirements incorporate a safety factor of ten, which accounts for any variation in the values derived. The safety factor is included because the QNFT test assumes a best fit situation. Applying the safety factor to the QNFT values accounts for worst case worksite situations. Once a good fit is assured using a quantitative fit test, a fit check still must be performed to provide confirmation that a good fit has been achieved.

In addition to the safeguards incorporated into the QNFT, three fit tests would be extremely costly to employers and would provide incentive for them to use a qualitative fit test instead.

(G) Use of Respirators

47) Issue: In the preamble to the proposed respiratory protection rule, OSHA discusses changes to the provision in the rule that prohibits employees with facial hair that interferes with the face-to-facepiece seal from wearing tight fitting respirators. Specifically, OSHA clarifies that "[t]he provision covers only tight fitting respirators and is not meant to be blanket prohibition on beards with respirators." (59 FR 58921)

Comment: ISEA supports the new provision prohibiting employees with facial hair that interferes with the face-to-facepiece seal from wearing tight fitting respirators, but only in those situations where the facial hair interferes with the face-to-facepiece seal.

Rationale: The proposed wording addresses the main issue - the fit of the respirator at the point of contact with the face or neck of the wearer - but does not make a blanket statement that could be interpreted as prohibiting all facial hair.

48) Issue: In the preamble to the proposed respiratory protection rule, OSHA invites comment on whether the rule should require that employers provide respirators that do not rely upon a tight facepiece fit to employees who have facial hair that interferes with the facepiece seal of tight fitting respirators. (59 FR 58921)

Comment: Where an employer is unwilling or unable to enforce a policy against facial hair intended to ensure that respirators fit adequately, ISEA believes OSHA should require the employer to provide respirators that do not rely upon a tight facepiece fit.

Rationale: There are a number of NIOSH-approved respirator types, particularly in the PAPR and supplied air categories, that do not rely upon a tight facepiece fit to give proper respiratory protection.

49) Issue: In Section (g)(8) of the proposed respiratory protection rule, OSHA states that "[t]he employer shall ensure that respirators are immediately repaired, or discarded and replaced when they are no longer in proper original working condition." (59 FR 58941)

Comment: ISEA recommends that the word "original" be deleted from this sentence.

Rationale: There is no way of knowing or verifying whether a respirator has been returned to its "original" condition.

(H) Maintenance and Care of Respirators

50) Issue: In the preamble to the proposed respiratory protection rule, OSHA states that "[i]t appears that the degree of severity of [an environmental condition that would cause deterioration] would be related to the tolerance of the particular equipment in question and would thus vary from model to model. OSHA invites comment on whether this approach is appropriate, or whether the conditions of storage should be specified in more detail. (59 FR 58924)

Comment: ISEA agrees that because the degree of severity of an environmental condition that would cause deterioration would be related to the tolerance of the particular equipment in question and would thus vary from model to model, there is no need to specify conditions of storage in more detail.

Rationale: Manufacturers specify any special instructions for storage of their equipment, where appropriate or necessary.

(I) Supplied Air Quality and Use

51) Issue: In the preamble to the proposed respiratory protection rule, OSHA proposes elimination of requirements for carbon monoxide (CO) monitors and alarms because of the allegedly low incident rate associated with compressor failures. (59 FR 58926)

Comment: ISEA recommends that OSHA adopt the requirements for carbon monoxide monitoring found in Section 10.5 of ANSI Z88.2-1992.

Rationale: For example, ANSI requires in Section 10.5.4.2 that "the air intake location shall be carefully selected, and monitored closely to ensure continued quality of air supply to the compressor." OSHA indicates it is aware of only one reported incident involving CO production by an oil lubricated compressor. However, there are more than one such incident on record. Carbon monoxide-related fatalities are too frequent and serious for OSHA to dismiss.

(K) Training

52) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on the proper frequency of training, particularly the need for increased training and more frequent refresher training for employees using SCBAs or emergency-use respirators. (59 FR 58929)

Comment: ISEA agrees that annual training for routine respirator use is adequate and that training for SCBA or emergency use respirators should be more frequent.

Rationale: More frequent training is justified for SCBA and emergency use respirators, based on the increased complexity of use and the severity of risk, which is much greater than under conditions of routine respirator use.

(L) Respiratory Protection Program Evaluation

53) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on the elements of the proposed respiratory program evaluation. (59 FR 58929)

Comment: ISEA recommends that OSHA adopt the list of factors cited in the preamble - comfort; resistance to breathing; fatigue; interference with vision; interference with communication; restriction of movement; interference with job performance; employee's confidence in the respirator's effectiveness - and include them in the proposed rule.

Rationale: Although the elements of the proposed respiratory program evaluation are appropriate and adequate, the factors listed in the preamble are not reproduced in section (1)(2)(i)-(v). These factors are central to whether employees actually wear respirators or not. They should be included in any initial assessment, as well as regular or random reviews.

The rule itself identifies the duties of the employer but not the means of fulfilling them. The means of fulfilling the employer's duties are laid out in the preamble, and this advice should appear in the text of the rule.

Potential problems with many of the listed factors can be alleviated by modern respirator designs and types, particularly PAPRs and supplied air respirators, and employees should be encouraged to regularly survey the range of equipment available.

(N) Substance-Specific Standards

54) Issue: In the preamble to the proposed respiratory protection rule, OSHA states that "for provisions in substance-specific standards which are more protective than the counterpart revised provisions of this standard, OSHA does not propose any changes . . . [I]n those cases where the existing respirator selection options in the substance-specific standards are less protective than would be permitted by the proposed NIOSH respirator selection tables, OSHA proposes to revise such permitted respirator selections to conform to [the respirator selection provisions in] paragraph (d)." (59 FR 58930)

Comment: ISEA recommends withholding any wholesale review or reassignment of protection factors until the forthcoming NIOSH module on APFs is complete. ISEA recognizes that, for certain hazards, it may be necessary to specify substance-specific protection factors that differ from the general industry values that will be set by NIOSH. However, this must be done using a coherent set of values reflecting modern respiratory equipment and practice.

Rationale: ISEA does not support the use of the APF values in the NIOSH Respirator Decision Logic. The NIOSH protection factor table does not even recognize the existence of several respirator classes (such as PAPRs with non-HEPA [high efficiency particulate air) filters or loose-fitting facepieces and supplied air respirators with continuous flow half-masks, hoods, helmets or loose-fitting facepieces) that are widely used with full NIOSH approval. Some form of recognition must be given to these alternatives.

Among the many anomalies in the NIOSH Respirator Decision Logic table, one of the most significant is the recommendation that a PAPR with a full face mask and a HEPA filter has the same protection factor (50) as a negative pressure respirator similarly equipped with a full face mask and a HEPA filter. Positive pressure systems like PAPRs are universally recognized as deserving higher protection factors than equivalent negative pressure systems. Unlike the 1987 NIOSH decision logic, the ANSI tables would give a protection factor of 1000 to PAPRs with HEPA filters and a protection factor of 100 for the negative system, reflecting modern practices.

OSHA intends to use the existing protection factors in the substance-specific standards where the APFs are lower than those values assigned in the Respirator Decision Logic. These APFs have been arrived at after serious consideration by OSHA and are based on workplace protection studies and other credible science. This is a prudent approach, taking into account the general nature of the NIOSH values. The same approach should be taken for any substance-specific protection factors that are higher than the NIOSH

values, if the studies on which they are based have any value. The approach proposed by OSHA, on the other hand, would reduce protection factors to the outdated and unscientific values in the NIOSH document or even lower, and would do so on an arbitrary basis.

The proposed NIOSH review of protection factors should be the surest way to measure the absolute and relative protection factors of the different respirators available today. As this major NIOSH initiative approaches, it would be inappropriate and untimely to introduce an arbitrary, interim set of APF values.

55) Issue: In the preamble to the proposed respiratory protection rule, OSHA states that "there are disposable respirators with elastomeric facepieces and high-efficiency filters which are said to provide fits as good as those provided by half-mask elastomeric respirators with replaceable high-efficiency filters. Such disposable respirators can be quantitatively fit tested, and are designed so that fit check procedures can be performed. OSHA is asking for comments on whether such respirators should be allowed to be used under the asbestos standard." (59 FR 58930-31)

Comment: ISEA recommends that OSHA eliminate the prohibition against using disposable respirators for protection against asbestos and inorganic arsenic.

Rationale: Classifying respirators in categories other than half masks, full face, etc., is design restrictive and, therefore, the only criteria should be the type of masks (half masks, full face, etc.) and their ability to be fit tested or checked according to the substance-specific standards. In many cases, disposable respirators are identical to non-disposable respirators, except that the cartridges or filter cannot be replaced. Additionally, recent studies indicate they can be fit checked as well as respirators with replaceable filters.

(P) Construction Advisory Committee

56) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment "on the appropriateness of using a cutoff level of one-half the PEL or TLV as the point where inadequate warning properties start, and on the effects such a level would have on of air-purifying respirator use." (59 FR 58932)

Comment: ISEA recommends that, rather than setting an arbitrary cutoff level to indicate where adequate warning properties start, OSHA should require

implementation of an administrative program that incorporates regularly scheduled cartridge changes.

Rationale: "Adequate" warning properties vary significantly from person to person and therefore are defined in very large ranges. If OSHA is going to use an "average" warning property, then the average should be at or near the hazardous exposure level. Regardless of the substance, if a hazardous substance is recognized as having poor or inadequate warning properties, then users should be required to implement an administrative program with regularly scheduled changing of cartridges after a certain exposure period. This is the most useful, safe, and effective method of handling such situations and allows the use of respirators that still can provide effective protection.

57) Issue: In the preamble to the proposed respiratory protection rule, OSHA indicates that the Construction Advisory Committee on Occupational Safety and Health (CACOSH) "recommended that the NIOSH Recommended Exposure Limit (REL) should also be used along with the TLV, and that whichever was lowest to be used in determining the hazardous exposure level. OSHA agrees that the NIOSH [RELs] are an appropriate source for exposure limits in the absence of a PEL. However, it is not clear that the lowest value from either the TLV or REL for a particular substance should be used. OSHA has received no comment on the appropriateness of the NIOSH RELs in the docket, and is requesting comments on how OSHA should require the use of the RELs by employers in establishing hazardous exposure levels for respirator use." (59 FR 58932)

Comment: ISEA recommends that RELs be used to determine hazardous exposure levels only in the absence of PELs or TLVs.

Rationale: RELs are often much lower than PELs or TLVs and may not always be supported by concrete scientific reasoning, but rather by the logic that "lower is better" and "any hazard is too much hazard." Although such reasoning is well intended, it is not only unreasonable in many cases, but also may create an economic burden to employers and to society if this logic were taken literally.

58) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on whether it should adopt the NIOSH limitations on maximum use concentration (MUC) as part of the revised rule. (59 FR 58932)

Comment: ISEA recommends that OSHA adopt a more general MUC formula that multiplies the APF (for a particular class of respirator) by the PEL or TLV

of the contaminant, whichever is lower, not to exceed the IDLH and takes into account such factors as warning properties, eye irritation, and oxygen deficiency.

Rationale: NIOSH no longer establishes MUCs and prohibits the use of MUC marking on approval labels and cartridges. An MUC is the most practical measure of what exposure level a respirator can be used against with a particular cartridge. To determine the MUC, one must have knowledge of whether a cartridge works for a particular substance. An employer is responsible for obtaining this information. For most common chemicals, respirator manufacturers provide this information, and many times will conduct testing upon request. This information must be known before any cartridge is used as protection against any substance, regardless of the exposure level.

59) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on the appropriate levels of odor threshold, proper test methods, and the appropriateness of requiring that odor threshold testing be conducted for individuals who must wear air-purifying respirators. (59 FR 58932)

Comment: ISEA recommends that, because of the huge variability of odor thresholds among individuals, employers should be required to evaluate each situation on a case-by-case basis and must take into account the sensitivity of the employees, level of exposure, and the hazard at the particular worksite.

Rationale: Normally, odor threshold levels are so variable that it would be impossible to set any rules capable of universal application.

60) Issue: In the preamble to the proposed respiratory protection rule, OSHA requests comment on whether monitoring should be mandatory for respirator selection, and, if so, what monitoring procedures should be used. OSHA also requests comment on the suggestion by CACOSH that, in the absence of monitoring, the most protective respirator should be used. (59 FR 58933)

Comment: ISEA recommends that monitoring or some other means of estimating exposure be conducted before a respirators is used. ISEA does not agree, however, that OSHA should require use of the most protective respirator in the absence of monitoring.

Rationale: In order to recommend any form of respiratory protection, one must understand what are the levels of exposure. It is not always necessary to

conduct exposure monitoring, as there are other ways to estimate exposure (e.g., knowledge of levels at comparable worksites, expertise of a health and safety professional). To equip someone with the most protective respirator does not always provide the best solution; even the most protective respirators have APFs and, therefore, an employer must still obtain information on the exposure levels. Additionally, always putting an employee in the most protective respirator can exacerbate inherent problems such as ergonomic, physiological, and safety problems.

XIV. Proposed Standard and Appendices

(i) Supplied air quality and use

61) Issue: In Section (i)(6) of the proposed respiratory protection rule, OSHA states that "[t]he employer shall use breathing gas containers marked in accordance with . . . Federal specification GG-13-00676b, September 23, 1976, Breathing apparatus, self-contained." (59 FR 58942)

Comment: ISEA recommends that breathing gas containers be marked in accordance with CGA C-7-1992 and that self-contained breathing apparatus cylinders be marked in accordance with DOT regulations and the certification/labeling requirements of NIOSH.

Rationale: The marking requirements in the proposed rule reference outdated federal standards. CGA C-7-1992, on the other hand, includes requirements for the proper identification of breathing air cylinders for other than SCBAs. The NIOSH labeling requirements cover SCBA cylinders as a component of a certified respirator.

(o) Appendixes

Appendix A: Fit Testing Procedures (Mandatory)

62) Issue: In Appendix A to the proposed respiratory protection rule, OSHA establishes quantitative fit testing procedures and methods of validating new procedures that ignores the primary modern test method: counting particles using ambient dust as the challenge agent. OSHA also ignores an even newer method that uses pressure sensing and degradation to measure fit factors. (59 FR 58943, -44, -46, -47)

Comment: ISEA recommends that OSHA revise Appendix A on quantitative fit testing to include tests that measure particle counts and use ambient dust as

the challenge agent. ISEA also recommends that OSHA include references to the pressure testing method.

Rationale: Since the particle counting method using ambient dust is now the most commonly used QNFT technique, employers may be confused by language in the proposal that fails to address this technique and only establishes requirements for validating other test methods. Employers may think they must validate the particle counting method independently. This test already has been validated, however, against both corn oil and sodium chloride. (For further discussion, see ISEA Issue #38.)

63) Issue: In Section II(A)(1) of Appendix A to the proposed respiratory protection rule, OSHA requires that "[t]he test subject shall be allowed to pick the most comfortable respirator from a selection including respirators of various sizes from different manufacturers." (59 FR 58944)

Comment: ISEA recommends that OSHA adopt the performance language from the ANSI Z88.2-1992 standard rather than the proscriptive language used in this proposal.

Rationale: See discussion in ISEA Issue #13.

64) Issue: In Section (II)(A)(14)(f) of Appendix A to the proposed respiratory protection rule, OSHA requires that "[t]he test subject shall grimace by smiling or frowning." (59 FR 58945)

Comment: ISEA does not agree that this exercise is appropriate for QLFT fit tests.

Rationale: OSHA's intent was to include this exercise to unseat respirators being fit tested and assure that after the grimace exercise there is a complete reseal. Although this may be appropriate for QNFT, where the fit test does not rely on any subjective evaluation, it is not appropriate for QLFT where grimacing may break the face to facepiece seal and fatigue the relevant senses. (For further discussion, see ISEA Issue #41.)

65) Issue: In Section II(B)(4)(c) of Appendix A to the proposed respiratory protection rule, OSHA requires that the individual performing the fit test "[a]ttach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute." (59 FR 58946)

Comment: ISEA recommends that OSHA add a requirement that an aspirator bulb be allowed or that OSHA specify a commercially available pump to be used when performing this test.

Rationale: Such a requirement would make it easier for employers to run this test. However, ISEA members are not aware of a commercially available pump to do this. Many members indicate that customers who already are performing this test for the asbestos, lead, or other OSHA standards that already require this test need guidance to know how to fulfill this obligation.

66) Issue: In Section II(C)(4)(h) of Appendix A to the proposed respiratory protection rule, OSHA states that "to successfully complete a QNFT, three successful fit tests are required. The results of each of the three independent fit tests must exceed the minimum fit factor needed for the class of respirator." (59 FR 58947)

Comment: ISEA considers three fit tests an unnecessary requirement that would create undue hardship for employers.

Rationale: See discussion in ISEA Issue #46.

XV. Proposed Substance-specific Standards Revisions

67) Issue: In Section XV of the proposed respiratory protection rule, OSHA's attempts to update several of its substance-specific standards are not complete. (There are some substance-specific standards affected by the new rule that are not referenced at all.) Nor are the substance-specific APF tables consistent with each other. (59 FR 58948-956)

Comment: ISEA recommends that OSHA redo the APF tables using the numbers in ANSI Z88.2-1992, be consistent and complete in the types of respirators recommended, and list all of its substance-specific standards affected by the change in respiratory protection requirements.

Rationale: The proposed rule appears to be in large part a dusted-off version of an earlier draft circulated by OSHA seven years ago. Based on the limited differences between that draft and the current proposal, ISEA has serious concerns about the agency's apparent failure to act expediently in issuing an updated standard. This rule is of utmost importance to both manufacturers and users, yet the agency has made little or no changes to it in seven years.

This absence of significant change since the 1988 draft is best evidenced by the failure of the current proposal to reflect any of the changes made in the interim to certain substance-specific standards referenced in the rule. The fact that the agency published a rule that contains so many inconsistencies with its own standards enhances the appearance that legitimate arguments made by outside parties were not given adequate agency consideration.

XIV. Conclusion

ISEA supports OSHA's efforts to update and revise its existing respiratory protection standard. Like OSHA, the Industrial Safety Equipment Association is committed to worker safety and protection. ISEA submits these comments in the interest of advancing that objective, and urges OSHA to consider our recommendations.

In particular, we urge OSHA to: adhere to the consensus of respiratory protection experts embodied in ANSI Standard Z88.2 1992; clarify when full medical evaluations and mere medical questionnaires should be required in the proposed rule; and eliminate the shortcomings in the proposed fit testing requirements.

ISEA would like to maintain open communication with OSHA in the development of this and future rulemakings. Research and development requirements and laboratory time are significant and costly for the manufacturing community. A close functional working relationship between manufacturers and regulators will help reduce costs to the market that often result from unrealistic performance requirements and help expedite the placement of advanced products on the market through focused research and development.

54-363A

THE ASSIGNED PROTECTION FACTOR ACCORDING TO ANSI

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The American National Standard for Respiratory Protection (ANSI Z88.2 1992) lists assigned protection factors (APFs) for various respirators. The committee that developed the APFs based their decisions on a review of available studies of respirator performance. If workplace studies were available, they formed the basis for the number assigned. If no such studies were available, then laboratory studies, design analogies and other information were used to decide what value to assign.

For half mask respirators four workplace protection factor studies were consulted to arrive at an APF. For loose fitting facepiece powered air purifying respirators, five workplace studies and two laboratory studies were reviewed. For full face air purifying, helmet/hooded PAPRs and most supplied air respirators no workplace studies were available. The assigned protection factor was based on laboratory studies or by analogy to other equipment. For the remaining respirators only single workplace protection factor studies were available and used by the committee to assign an APF.

The data base available to the ANSI committee was limited. Studies completed after the ANSI committee finished their deliberations when added to the data they used continue to support the APFs assigned by ANSI.

Introduction

The assigned protection factor (APF) is defined as the minimum expected workplace level of respiratory protection that would be provided by a properly functioning respirator or class of respirators, to a stated percentage of properly fitted and trained users[1]. The APF is used to select respirators based on the expected concentration of a contaminant in the workplace, where a respirator with an APF greater than the hazard ratio is chosen as the minimum required respirator[2].

In developing the list of APFs, the ANSI committee based their decisions on a review of available studies of respirator performance[3]. If workplace protection factor studies were available, they formed the basis for the number assigned. If no such studies were available, then laboratory studies, design analogies and other information were used to decide what value to assign. For each type of respirator a summary of the workplace and laboratory studies used by the ANSI committee and studies completed after their review are given below.

The summary statistics for each study are shown in Tables 1 through 3. For each study, the statistics have been recalculated where inside samples were below the detection limit of the analytical method to make the calculations uniform and to minimize the bias for estimates of the geometric mean and geometric standard deviation. Waters has shown that a value of 60 to 70% of the detection limit when substituted for samples with concentrations below the detection limit minimizes the bias in estimating these statistical parameters[4]. A value that was 70% of the detection limit, was used.

Air Purifying Respirators

An air purifying respirators is a respirator in which ambient air is passed through an air purifying element that removes the contaminant(s)[2]. Air is passed through the air-purifying element by means of the breathing action (negative pressure respirators) or by a blower (powered air purifying respirators or PAPRs). Negative pressure respirators are equipped with either quarter mask, half mask or full facepieces. ANSI places quarter masks and elastomeric and disposable half masks in the same category of half masks. ANSI classifies PAPRs as half mask, full face, helmet/hoods or loose fitting facepieces.

Half Mask Negative Pressure Respirators

Nelson[5] reviewed a number of workplace protection factor studies that included those used by the ANSI committee and studies that were conducted at a later date. Table 1 lists the statistical data from these studies. Based on the estimates of the 5th percentile for these studies, the ANSI committee assigned an APF of ten for half mask respirators[6]. The study by Reed was not considered to be a valid indicator of performance by the ANSI committee. The analytical method used to measure the dust inside the facepiece was mass which is nonspecific. The dust was a cement product so water of hydration was included

in the measurement of the mass. Also, an improperly conducted quantitative fit test was used.

Nelson concluded that the assigned protection factor of ten was appropriate based on a statistical analysis that showed the 5th percentile of the WPF data to be greater than ten. The studies he used included the studies used by ANSI and other studies conducted after the ANSI committee concluded their deliberations.

Full Facepiece Negative Pressure Respirators

The ANSI committee did not find any data on full facepiece negative pressure respirators that was conducted after the APF of 100 was assigned by the 1980 ANSI standard[6]. Based on not finding any new data, no change in the APF was warranted.

Since then Colton reported on a WPF study in secondary lead smelter[7].The people who participated were quantitatively fit tested with a minimum fit factor of 500 required to participate. Samples were analyzed by PIXE with a detection limit of 10ng. per filter. Particle size analysis showed that both fume and dust were present. Approximately 65% of the particles were greater than 10 μm, and 15% were less than 0.9 μm. Thirty-two WPF values were obtained. The geometric mean WPF was 4790, with a geometric standard deviation of 7. The best estimate of the 5th percentile is 194 which is consistent with the ANSI APF of 100.

Half Mask Powered Air Purifying Respirators

Myers and Peach studied the performance of half and full facepiece PAPRs equipped with high efficiency filters (HEPA) in a silica bagging operation[8]. Samples were collected on 5 μm pore size polyvinyl chloride filters, analyzed gravimetrically and by x-ray diffraction. The detection limit for the mass determination was 0.03 mg/sample,

for the x-ray diffraction method, 0.005 mg/sample. Samples were collected for multiple wearings, with the PAPRs removed during meal times and other breaks. Individual samples were collected for morning and afternoon shifts. Four workers were involved. The mass mean aerodynamic diameter was measured at 5.5 and 5.8 μm on two of the three days the study was conducted. They reported leakage of silica occurred where the breathing tube connects to the blower, which could have let unfiltered air pass the filter and enter the blower housing. Thus this study may not predict actual performance of a half mask PAPR.

Lenhart and Campbell studied the performance of a half mask PAPR equipped with HEPA filters in a primary lead smelter[9]. Twenty-five people participated. To participate each had to pass a quantitative fit test with a MSA half mask respirator with a fit factor of 250. The samples were analyzed by atomic absorption with a detection limit of 2-5 μg per sample. Inside the facepiece samples (C_i) that analyzed at less than 10 μg, were analyzed by graphite furnace atomic absorption with a detection limit of 0.2 μg per sample. The study was conducted in two separate areas of the facility, the sinter plant area particle size had mass mean aerodynamic diameters of 9-16 μm, while the furnace area had mass mean aerodynamic diameters of 1-8 μm. Three C_i samples were below the limit of detection. Using a value of 70% of the detection limit, the geometric mean WPF is 431, the best estimate of the 5th percentile is 58.

daRoza *et. al.* reported on a simulated workplace study an a half mask PAPR[10]. The penetration into the facepiece was measured during exercise on a tread mill. Air flow was controlled to the facepiece by replacing the battery pack with a DC power supply and varying the voltage to obtain the air flow desired. Simulated workplace protection factors were measured by light scattering photometer. For the half facepiece PAPR, the penetration remained constant at the varying work levels with a simulated workplace protection factor of approximately 5000.

Skaggs *et. al.* reported on simulated workplace studies with a MSA half mask PAPR [11]. Simulated workplace protection factors were measured by light scattering photometry in a chamber with temperature and humidity controls. Various exercises were performed such as shoveling, hammering, moving blocks, pounding a board with a sledge hammer. The mean simulated workplace protection factors for the various temperatures and humidities were from 14,300 to 20,000.

Since the Myers and Peach data may not have been a realistic estimate of performance, the Lenhart data was the only WPF data available to the ANSI committee[6]. With a geometric mean WPF of 431 and a 5th percentile of 58, the APF is not inconsistent with this data. The two simulated workplace studies are consistent with the APF. No new studies have been reported on the half mask PAPR since the ANSI committee completed their work.

Full Facepiece Powered Air Purifying Respirators

The committee did not have any WPF data on full face PAPRs[6]. A value of 1,000 was chosen for the APF based on being consistent with the APF chosen for the helmet/hood style as discussed below. Some felt that the full face PAPR would perform better than a helmet or hooded PAPR, thus choosing the same value would also be a conservative approach.

The committee also reviewed a report by Ayer on a laboratory study of full facepiece PAPRs equipped with HEPA filters in a chamber with a silica dust aerosol[12]. Samples inside the facepiece were collected at 12 liter/minute, outside samples at approximately 1.5 liters/minute. Four people participated in the test, and were sampled while moving bags of material inside the chamber. Samples were analyzed by weighing the filters. The simulated protection factor obtained showed a correlation with the chamber concentration. When the data were divided into two groups, low and high

chamber concentration the mean simulated protection factors were 3389 (low) and 5580 (high). These data were considered consistent with the APF chosen.

Since the APF was assigned, Colton *et. al.* reported on a study with a full facepiece PAPR in a secondary lead smelter[13]. Twenty people participated who were each quantitatively fit tested with a TSI Portacount® fit test unit. The minimum fit factor required was 500. Samples were collected for a period of 1 to 4 hours. All samples were analyzed for lead by PIXE, with a detection limit of 10 ng/sample. Samples less than 1000 times the detection limit were excluded from the analysis. The 5th percentile WPF of 1400 is consistent with the APF of 1000.

Helmet/Hooded Powered Air Purifying Respirators

There were no WPF studies available for PAPRs with helmets or hoods. The APF was assigned by the ANSI committee based on analogy to an air line respirator operating at same flow rates[6].

Since then, Keys *et. al.* reported on the performance of three helmet/hood type PAPRs in a pharmaceutical manufacturing facility[14]. The respirators were a Racal Breathe Easy 10, Bullard Quantum and the 3M Whitecap II. Inside the inlet covering samples were collected for 30 minutes to 3 hours and analyzed for estradiol benzoate by a radio immunoassay technique with a limit of quantification of 50 picograms per sample. Outside the respirator samples were analyzed by HPLC. Probe loss was determined to be less than 1%. The best estimate of the 5th percentile WPF, 1470, is consistent with the APF assigned by the ANSI committee.

Loose Fitting Facepiece Powered Air Purifying Respirators

The committee had several WPF studies on loose fitting facepiece PAPRs to guide them on assigning an APF. The summary statistics for the studies are shown in Table II.

Meyers *et. al.* studied the performance of the 3M Airhat ® and the Racal model AH3 loose fitting facepiece type PAPRs equipped with dust/mist filters in a battery manufacturing facility[15]. Twelve workers participated in the study with samples collected for the full 8 hour shift with the sampling pumps turned off during the times the PAPR was not being worn. The inside the facepiece probe was located approximately 1-2 inches from the mouth. The inside the facepiece samples were analyzed by graphite furnace atomic absorption with a detection limit of 0.3 μg per sample, the outside samples by atomic absorption with a detection limit of 3 μg per sample. The particles in the workplace had a mass mean aerodynamic diameter of 17 μm. The geometric mean WPF was 127 and the best estimate of the 5th percentile WPF was 32.

Gosselink *et. al.* studied the performance of the 3M Airhat® with HEPA filters in a brake manufacturing facility[16]. The asbestos fibers were analyzed by phase contrast microscopy, with a modification to increase the number of fields counted to increase sensitivity. The detection limit was 1 fiber/filter. The geometric mean WPF was 199 and the best estimate of the 5th percentile WPF was 41.

Myers *et. al.* studied the performance of a Racal AH3 and a 3M Airhat® loose fitting facepiece PAPRs equipped with high efficiency filters in a secondary lead smelter[17]. Twelve people participated and each was given a quantitative fit test before being included in the study. A fit factor of 1000 was required, and since no one had a fit factor less than 1000, the fit test was not a factor in the study outcome. Samples were collected during the entire shift while the respirator was worn. The inside the facepiece

samples were analyzed by graphite furnace atomic absorption with a detection limit of 0.3 μg per sample, the outside samples by atomic absorption with a detection limit of 3 μg per sample. The particle size of the aerosol varied by area of the plant. At the furnace and caster, approximately 35% of the aerosol was greater than 17 μm, and 30% smaller than 0.68 μm. At the blast furnace, 60% was greater than 17 μm and 8% smaller than 0.68 μm. The geometric mean WPF was 182 and the best estimate of the 5th percentile WPF was 32.

Que Hee and Lawrence studied the performance of a Racal Airstream AH3 and AH3-1 loose fitting facepiece respirator equipped with high efficiency filters for two job classes in a brass foundry[18]. For furnace room attendants samples were collected for four to eight hours and included breaks and lunch. For the ladle attendants, samples were collected only during pouring which lasted three to four hours. Seven people participated in the study. Samples were analyzed by flame atomic absorption spectroscopy. In this study, the C_i samples included time in which the shield of the PAPR was raised, making most of the data an effective protection factor study. Also the authors noted that low flows were measured due to low battery charge. The committee did not use the information from this study in setting an APF.

Dixon *et. al.* performed a program protection factor (PGF) study on the 3M Airhat® loose fitting facepiece PAPR equipped with dust/mist filters[19]. As opposed to WPF studies where the equipment is verified to be properly working and used, the PPF data is collected as the respirator is used in the workplace without any checks on the function of the equipment and its use. Seven people participated in the study. Samples were collected for the duration of a specific task that lasted 30 minutes to 2 hours. Analysis of samples was by PIXE with a limit of detection of 10 to 100 ng per filter. The geometric mean PGF was 230, but the data did not play a role in the decision to assign an APF.

Two simulated workplace studies were also reviewed, one by daRoza the other by Skaggs that were previously described. daRoza tested two loose fitting facepiece PAPR's, a 3M Airhat® and Racal Breathe Easy 1. Skaggs tested a 3M Airhat® and Racal AH3 loose fitting facepiece respirators. daRoza found mean fit factors of 100 and 10 when the work rate was at the maximum. Skaggs found mean SWPF's of 19000 to 5600 for the 3M Airhat® and 1200 to 3500 for the Racal AH3.

After reviewing the WPF studies described above, the ANSI committee concluded an APF of 25 was appropriate for loose fitting facepiece PAPRs[6].

Since the committee completed their work, two more studies have been reported. First, Gaboury and Burd measured the work place performance of a Racal Breathe-Easy PAPR equipped with HEPA filters[20]. They measured benzo-alpha-pyrene, which is contained in the benzene soluble materials present in the particulate in the aluminum smelting process. Benzo-alpha-pyrene was detected at 0.003 ug/m3. Seventy five percent of the benzo-alpha-pyrene was contained in an aerosol with an aerodynamic diameter of 0.93 μm. Samples were collected outside the respirator at a point above the visor. Because of the heat load in the production areas, workers spend one half hour each hour in a cool environment, for this time period, the sampling was stopped. Therefore each data point equals the WPF for multiple wearings in each work shift. Both bearded and clean shaven people were included in the study. The geometric mean WPF was 1410, the best estimate of the 5th percentile was 306.

Stokes *et. al.* studied the 3M Airhat®, loose fitting facepiece PAPR, equipped with dust/mist or HEPA filters and a version of the equipment with a Tyvek® shroud[21]. The study was conducted in a roofing granule production plant and measured silica dust. Five people participated. Samples were collected for 30 minutes to 1 hour. Only samples with inside concentration greater than 25 or 100 times the mean blank concentration

were included in their analysis. The geometric mean WPF was 1530, the best estimate of the 5th percentile was 85.

These studies support the APF assigned by the ANSI committee.

Atmosphere-supplying respirators

Atmosphere-supplying respirators are a class of respirators that supply a respirable atmosphere, independent of the workplace atmosphere[2]. One type is commonly called an air line respirator and operates in one of three modes: demand, continuous flow or pressure demand. Demand and pressure demand can be equipped with either a half face or full facepiece inlet coverings. The continuous flow type can also be equipped with a helmet/hood or a loose fitting facepiece. A second type of atmosphere supplying respirator is equipped with a self contained air supply. These are either the self contained breathing apparatus or in combination with a pressure demand supplied air line respirator. A summary of the information used by the ANSI committee is presented in Table III.

Demand supplied air, half or full facepiece

The ANSI committee did not find any new information on these types of units. The APF of ten was based on analogy to the air purifying respirators[6].

Continuous Flow Atmosphere Supplying Respirators

There were no workplace studies on half mask or loose fitting facepiece supplied air respirators. The APF was based on analogy to the PAPRs where the same air flows are required by NIOSH for certification[6]. For the full facepiece supplied air respirator, there was no data, the APF was set to be the same as the helmet/hood style with no evidence to set it either higher or lower.

For helmet/hood type supplied air respirators, the committee was briefed on a workplace protection factor study by Johnston[6]. The study was later reported at a technical conference[22].The study was conducted during sand blasting of a barge. Samples were analyzed for silica by PIXE. They found a relationship between the loading on the outside filters and the mean WPF found. When samples with mean loadings greater than 1000 times the mean blank loading are used to estimate the 5th percentile, the estimate is 1038. Skaggs studied a helmet/hood type in the simulated workplace study. The mean simulated workplace protection factors for the various conditions ranged from 7500 to 20,000.Based on this information, an APF of 1000 was assigned[6].

Pressure Demand Respirators

Pressure demand respirators can have the air supply delivered by an airline, a self contained cylinder or in combination. There was no workplace data on either a half mask or full face pressure demand supplied air respirators. Skaggs did include a full face airline model in their study, the mean simulated workplace protection factors for the various conditions ranged from 8500 to 20,000. daRoza reported to the committee on a simulated workplace study with a self contained air supply[6]. The respirators were a MSA SCBA with regulators that comply with the air flow requirements of the NFPA standard[23]. Simulated workplace protection factors were measured while the people walked on a treadmill with the speed and elevation set to achieve a work rate of 80% of the maximum heart rate. The lower 95% confidence level of the geometric mean was 6000, the best estimate of the 5th percentile was 300. One person had simulated workplace protection factors less than 1000.

The APF for all pressure demand respirators was set based on analogy to PAPRs and continuous flow supplied air systems[6]. The committee believed that a higher APF because of the pressure demand feature was not warranted, rather the total air flow was

considered critical. For self contained breathing apparatus, no APF was assigned. During the balloting process, consensus could not be reached on an APF. The committee felt the need to call attention to the fact that data has shown the performance of this type of respirator may not be as good as previously measured in quantitative fit test chambers. Since SCBA's are generally chosen not by the need for a definitive level of protection, but rather than for specific situations (e.g. fire fighting, emergencies) and they are considered the highest level of protection available for these types of situations, the APF is considered less meaningful.

Conclusions

The assigned protection factor (APF) is defined as the minimum expected workplace level of respiratory protection that would be provided by a properly functioning respirator or class of respirators, to a stated percentage of properly fitted and trained users[1]. For most types of respirators very little data beyond single workplace studies are available for analysis and estimating performance. Other types of information such as design analogy are needed to assign an APF.

The stated percentage of properly fitted users has not been set by any group. In reporting the results of WPF studies, the best estimate of the 5th percentile has been reported as representing an estimate of the APF by a number of authors[7-9,13-17,20-24,31-33,35]. The ANSI committee used the estimate of the 5th percentile as one of the factors in judging the results of WPF studies[6]. There appears to be some consensus that the APF should be set so that at least 95% of the time it is achieved.

Table I: Workplace Protection Factors
Negative Pressure Air Purifying Respirators

Half Mask				
Studies Available to Committee				
	N	Geometric Mean	GSD	Best Estimate 5th Perct.
Dixon[24]	42	3360	4.8	254
Reed[25] (A)	19	18	3.17	2.7
Lenhart [26]	25	166	3.8	18
Nelson [27]	76	258	5.2	17
Subsequent Data				
Gosselink [28]	44	96	2.3	24
Gaboury [29]	18	47	2.5	10
Colton-welding [30]	32	147	2.5	33
Myers [31]	153	346	7.2	14
Johnston [32](A)	18	44.8	2.85	8
Colton -brass foundry[33] (B)	38	28.2	2.06	8.6
Colton- Al smelter[34](B)	42	469	3.87	50
Galvin[35](B)	63	75	3.1	11.7
Wallis[36](B)	70	50	3.5	7.5
Full Facepiece				
No WPF Studies Available Decision: Since no new data, no change from 1980 standard				
Subsequent Data				
Colton	32	4790	7	194

(A) ANSI and Nelson concluded sampling bias may have been a factor in the WPF measured.
(B) Nelson concluded sampling bias may have been a factor in the WPF measured.

Table II: Workplace Protection Factors
Powered Air Purifying Respirators

Half Mask	N	GM	GSD	5th
Lenhart	25	431	3.4	58
Myers & Peach	10	54	2.2	12
daRoza(Simulated Work Data)	—	5000	—	—
Skaggs(Simulated Work Data)	—	14300-20000	—	—
Full Facepiece				
Ayer (Simulated Work Data)	—	—	—	—
Subsequent Data				
Colton	55	10300	3.4	1400
Helmet/Hood				
Decision based on analogy to atmosphere supplied helmet/hood data				
Subsequent Data				
Keys	60	10400	3.3	1470
Loose Fitting Facepiece				
Myers- battery	47	127	2.3	32
Gosselink	7	199	2.6	41
Myers-- smelter	43	182	3.3	32
Que Hee	—	—	—	—
daRoza(Simulated Work Data)	—	—	—	—
Skaggs(Simulated Work Data)	—	—	—	—
Dixon (Program Protection Factor)	—	230	—	—
Subsequent Data				
Gaboury	20	1410	2.5	306
Stokes	39	1530	5.8	85

Where: N = number of data, GM = Geometric Mean, GSD = Geometric Standard Deviation, 5th = Best Estimate of 5th Percentile

Table III: Workplace Protection Factors
Atmosphere Supplying Respirators

Demand				
Half Mask	No WPF data, APF assigned based on analogy to negative pressure respirators.			
Full Facepiece	No WPF data, APF assigned based on analogy to negative pressure respirators.			
Continuous Flow				
Half Mask	No WPF data, APF assigned based on analogy to powered air purifying respirators.			
Full Face	No WPF data, APF assigned based on analogy to powered air purifying respirator.			
Helmet/Hood	N	GM	GSD	5th
Johnston[C]	15	4076	2.3	1038
Loosefitting Facepiece	No WPF data, APF assigned based on analogy to powered air purifying respirator.			
Pressure Demand				
Half Mask	No WPF data, APF assigned based on analogy to powered air purifying respirator.			
Full Facepiece	No WPF data, decision based on daRoza (Simulated Work Data) and by analogy to continuous flow respirator.			

[C] WPFs with outside filter weights > 1000X the background level on the blanks

Where N = number of data, GM = geometric mean, GSD = geometric standard deviation 5th = best estimate of the 5th percentile

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12/09/94

ISEA ATTACHMENT #2, Isoamyl Acetate Fit Test 54-363B

Statistical results showing the performance of the Isoamyl Acetate qualitative fit tests using the ANSI Z88.10 Protocol requirements plus some additional criterion is as follows:

1. The statistic is identified.
2. Defined as a proportion and calculated.
3. Determine confidence limits on the statistic.
   (95% Confidence Limits = $1.96\ [P(1.00 - P)/n]^{1/2}$; Where P = Study Result)

Validation Statistic	Calculation Method	Test Requirement	Study Results	Confidence Limits (95%)
Test Sensitivity	$Fail_{FF<1000}/Total_{FF<1000}$	≥ 0.95	0.981	$\pm$ 0.026
Predictive Value of QLFT Pass	$Pass_{FF\geq 1000}$/Total Pass	≥ 0.95	0.973	$\pm$ 0.036
Test Specificity	$Pass_{FF\geq 1000}/Total_{FF>1000}$	>0.5	0.635	$\pm$ 0.088
Predictive Value of QLFT Failure	$Fail_{FF<1000}$/Total Fail	>0.5	0.708	$\pm$ 0.074
Alpha error (α)	$Fail_{FF\geq 1000}/Total_{FF\geq 1000}$	≤ 0.5	0.365	$\pm$ 0.088
Beta error (β)	$Pass_{FF<1000}/Total_{FF<1000}$	≤ 0.05	0.019	$\pm$ 0.026

Where: $Fail_{FF<1000}$ = Number of qualitative fit test failures where fit factor was <1000

$Pass_{FF<1000}$ = Number of qualitative fit test passes where fit factor was <1000

$Total_{FF<1000}$ = Total number of tests where fit factor was <1000

$Fail_{FF\geq 1000}$ = Number of qualitative fit test failures where fit factor was $\geq$1000

$Pass_{FF\geq 1000}$ = Number of qualitative fit test passes where fit factor was $\geq$1000

$Total_{FF\geq 1000}$ = Total number of fit tests where fit factor was $\geq$1000

Total Pass = Total number of qualitative fit test passes

Total Fail = Total number of qualitative fit test failures

Confidence limits can be placed on this type of results by assuming a binomial distribution. Since the test data must have a quantitative value of <RFF (Required Fit Factor) or ≥ RFF and either pass or fail the qualitative test, all the results will fit into a 2X2 table.

Example of using 137 paired tests for determining the best estimate and a 95% confidence limit around the "predictive value for a pass" with the RFF value set at 1000.

	RFF < 1000	RFF ≥ 1000	Totals
Fail	49	10	59
Pass	1	77	78
Totals	50	87	**137**

$77/(1+77) = 0.987$

$0.987 \pm 1.960[0.987(1-0.987)/78]^{1/2}$

0.987 ± 0.025

11/12/93

ROW	PassPop	FailPop
1	332	30
2	705	40
3	1016	50
4	1100	50
5	1176	70
6	1266	70
7	1499	70
8	1700	70
9	1754	90
10	1874	90
11	2160	99
12	2200	100
13	2399	110
14	2900	120
15	2926	160
16	3910	194
17	3970	225
18	3990	239
19	4347	239
20	4740	240
21	4800	260
22	4880	270
23	4900	276
24	5800	284
25	6000	290
26	6382	293
27	6530	297
28	6600	319
29	7000	320
30	7400	330
31	8163	332
32	8320	335
33	8490	349
34	9200	352
35	9500	357
36	9677	363
37	10000	365
38	10000	371
39	10000	372
40	10000	376
41	10000	380
42	10000	389
43	10000	390
44	10000	398
45	10000	408
46	10000	420
47	10000	431
48	10000	444
49	10000	454
50	10000	460
51	10000	463
52	10000	465
53	10000	472
54	10000	476
55	10000	487
56	10000	490
57	10256	495

58	12245	500
59	15000	508
60	15113	535
61	17647	535
62	21277	535
63	21428	540
64	25000	566
65	25000	576
66	28169	580
67	28571	581
68	37037	588
69	37500	594
70	38462	594
71	46154	599
72	52632	600
73	66667	625
74	66667	630
75	100000	659
76		659
77		659
78		666
79		670
80		674
81		674
82		674
83		689
84		710
85		720
86		720
87		729
88		731
89		752
90		790
91		793
92		833
93		840
94		840
95		860
96		890
97		895
98		899
99		934
100		961
101		970
102		980
103		1020
104		1034
105		1063
106		1075
107		1100
108		1102
109		1111
110		1123
111		1163
112		1176
113		1263
114		1265
115		1270
116		1299
117		1366

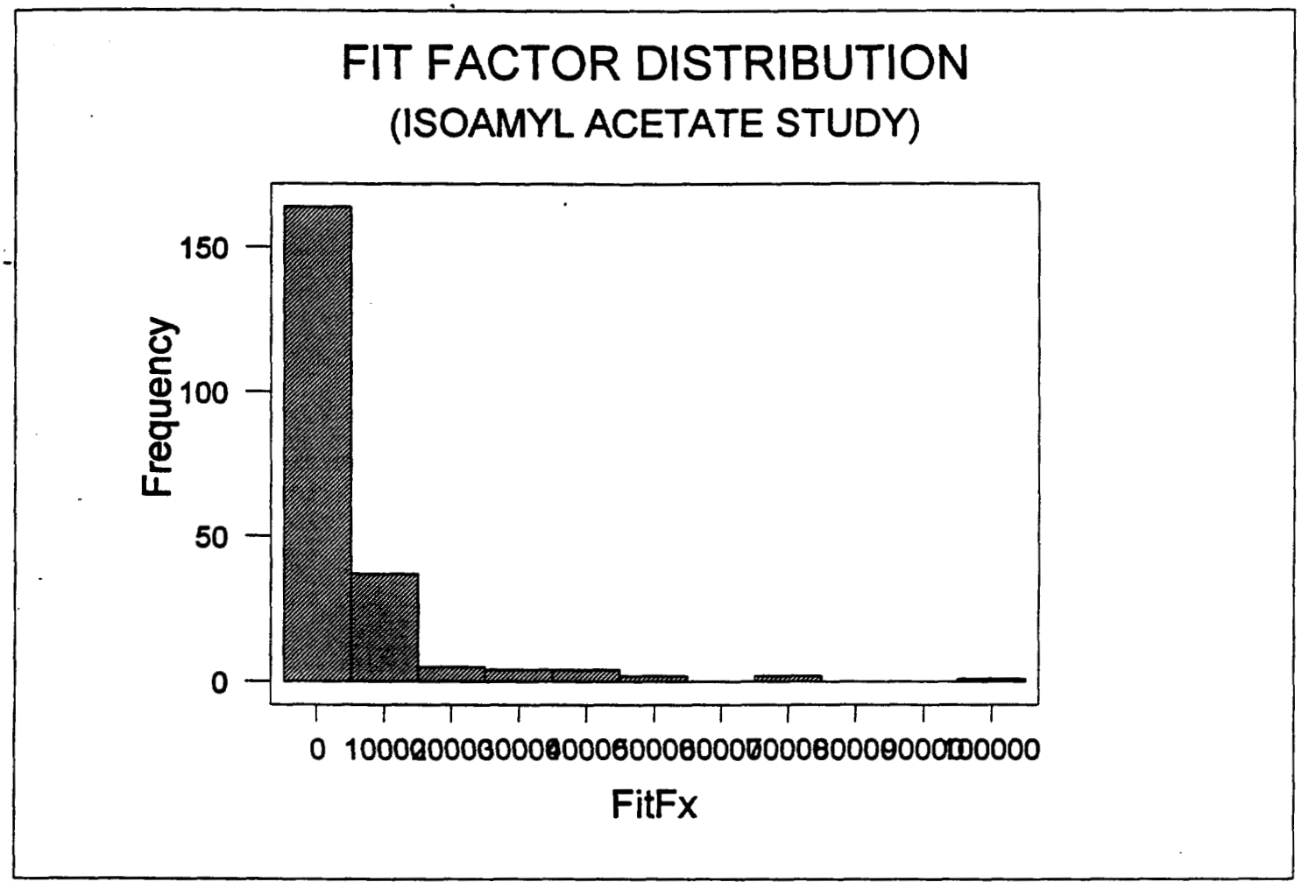
118	1389
119	1400
120	1445
121	1450
122	1470
123	1515
124	1600
125	1608
126	1612
127	1775
128	1818
129	1923
130	1967
131	1999
132	2105
133	2214
134	2222
135	2255
136	2400
137	2608
138	2857
139	2900
140	3275
141	3749
142	6593
143	8695
144	37037

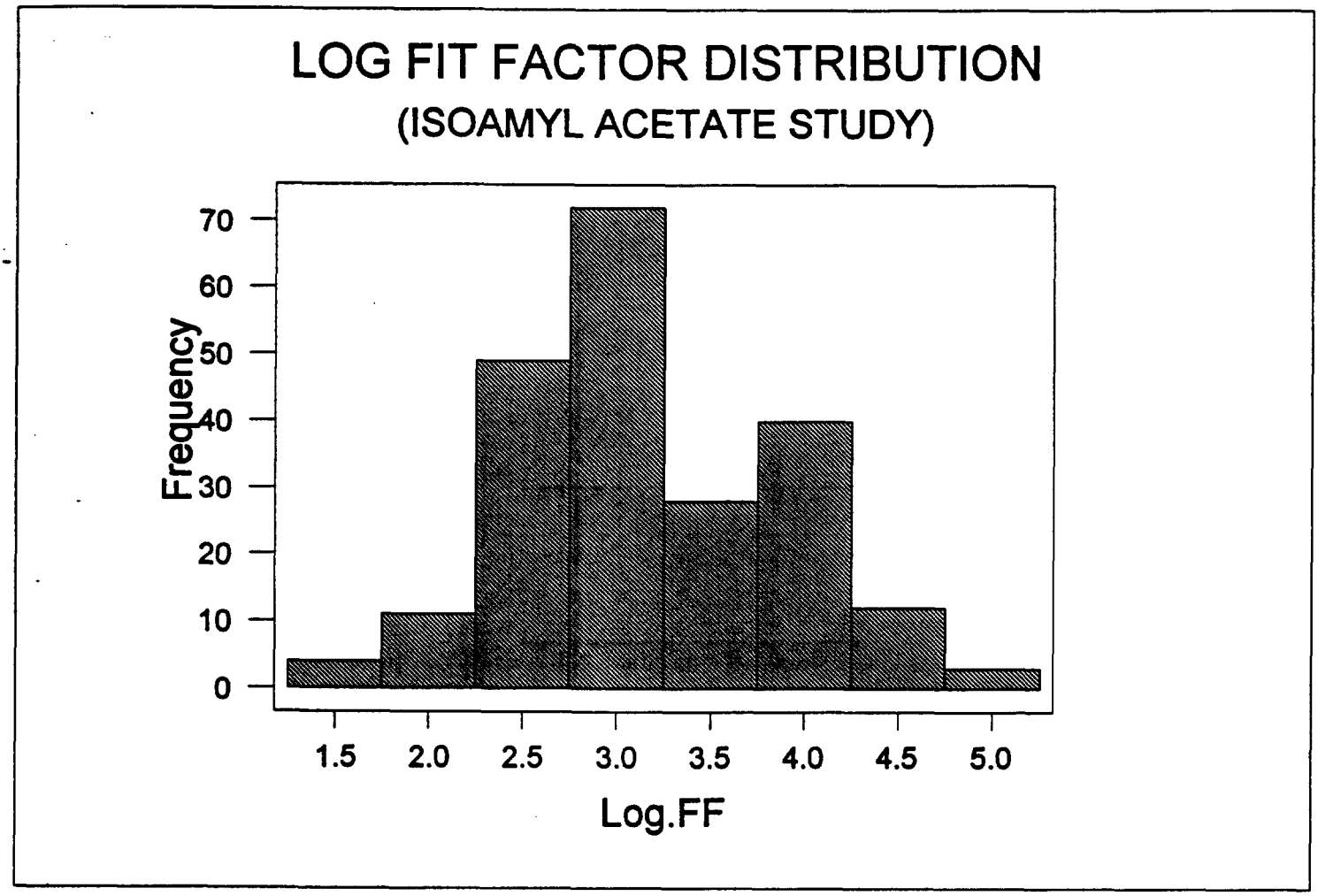
```
MTB > DESC C4  C7  C8
```

	N	MEAN	MEDIAN	TRMEAN	STDEV	SEMEAN
FitFx	219	5441	1100	3310	11923	806
PassPop	75	13659	10000	10975	17176	1983
FailPop	144	1162	612	783	3192	266

	MIN	MAX	Q1	Q3
FitFx	30	100000	476	5800
PassPop	332	100000	4347	10256
FailPop	30	37037	363	1109

```
MTB >
```


FIT FACTOR DISTRIBUTION
(ISOAMYL ACETATE STUDY)
Frequency
150
100
50
0
0
FitFx


LOG FIT FACTOR DISTRIBUTION
(ISOAMYL ACETATE STUDY)
Frequency
70
60
50
40
30
20
10
0
1.5
2.0
2.5
3.0
3.5
4.0
4.5
5.0
Log.FF

ISOAMYL ACEATE RESPONSE FOR QUANTITATIVE & QUALITATIVE TESTS

Test Results:
Combined Panels
****

QLFT	QNFT					
	< 30	<100	<300	<1000	<3000	<10000
Pass	0	0	0	2	15	36
Fail	0	11	27	102	139	143
Total	0	11	27	104	154	179
	≥30	≥100	≥300	≥1000	≥3000	≥10000
Pass	75	75	75	73	60	39
Fail	144	133	117	42	5	1
Total	219	208	192	115	65	40

No. of Tests: 219

Test Sensitivity → $\frac{F(<ff)}{P(<ff)+F(<ff)} \geq 0.95$

ff (30)	1.00
ff (100)	1.00
ff(300)	1.00
ff(1000)	0.98

Predictive Value of a Pass → $\frac{P(\geq ff)}{P(\geq ff)+P(<ff)} \geq 0.95$

ff (10)	1.00
ff (30)	1.00
ff(100)	1.00
ff(1000)	0.97

Test Specificity → $\frac{P(\geq ff)}{P(\geq ff)+F(\geq ff)} > 0.5$

ff (10)	0.34
ff (30)	0.36
ff(100)	0.39
ff(1000)	0.63

Predictive Value of a Fail → $\frac{F(<ff)}{F(\geq ff)+F(<ff)} > 0.5$

ff (10)	0.00
ff (30)	0.08
ff(100)	0.19
ff(1000)	0.71

False Positive , alpha → $\frac{F(\geq ff)}{F(\geq ff)+P(\geq ff)} = X$

ff (10)	0.66
ff (30)	0.64
ff(100)	0.61
ff(1000)	0.37

False Negative, beta → $\frac{P(<ff)}{P(<ff)+F(<ff)} = X$

ff (10)	0.00
ff (30)	0.00
ff(100)	0.00
ff(1000)	0.02

FREQUENCY DATA ANALYSIS

	FF < 1000	FF ≥ 1000	
Fail	a [redacted]	b [redacted]	144
Pass	c [redacted]	d [redacted]	75
	104	115	[redacted]

			Best Estimate		95% C.L.	Range LCL		UCL
(Beta)	$\frac{c}{a + c}$	≤ 0.05	0.019	±	0.026	0.000	- - -	0.046
(Pred Pass)	$\frac{d}{c + d}$	≥ 0.95	0.973	±	0.036	0.937	- - -	1.010
(Alpha)	$\frac{b}{b + d}$	≤ 0.50	0.365	±	0.088	0.277	- - -	0.453
(Pred Fail)	$\frac{a}{a + b}$	≥ 0.50	0.708	±	0.074	0.634	- - -	0.783

FREQUENCY DATA ANALYSIS

	FF < 3000	FF ≥ 3000	
Fail	a [redacted]	b [redacted]	144
Pass	c [redacted]	d [redacted]	75
	154	65	[redacted]

			Best Estimate		95% C.L.	Range LCL		UCL
(Beta)	$\frac{c}{a + c}$	≤ 0.05	0.097	±	0.047	0.051	- - -	0.144
(Pred Pass)	$\frac{d}{c + d}$	≥ 0.95	0.800	±	0.091	0.709	- - -	0.891
(Alpha)	$\frac{b}{b + d}$	≤ 0.50	0.077	±	0.065	0.012	- - -	0.142
(Pred Fail)	$\frac{a}{a + b}$	≥ 0.50	0.965	±	0.030	0.935	- - -	0.995

FREQUENCY DATA ANALYSIS

	FF < 10000	FF ≥ 10000	
Fail	a [redacted]	b [redacted]	144
Pass	c [redacted]	d [redacted]	75
	179	40	[redacted]

				Best Estimate		95% C.L.	Range LCL		UCL
(Beta)	$\frac{c}{a + c}$	≤	0.05	0.201	±	0.059	0.142	- - -	0.260
(Pred Pass)	$\frac{d}{c + d}$	≥	0.95	0.520	±	0.113	0.407	- - -	0.633
(Alpha)	$\frac{b}{b + d}$	≤	0.50	0.025	±	0.048	-0.023	- - -	0.073
(Pred Fail)	$\frac{a}{a + b}$	≥	0.50	0.993	±	0.014	0.979	- - -	1.007

54-363C

U.S. Department of Labor

Assistant Secretary for Occupational Safety and Health Washington, D.C. 20210

June 24, 1994

MEMORANDUM FOR: REGIONAL ADMINISTRATORS

FROM: JAMES W. STANLEY
DEPUTY ASSISTANT SECRETARY

SUBJECT: Quantitative Respirator Fit Testing Requirements and Compliance

This memorandum replaces the November 8, 1988, memorandum to you concerning Portacount Fit Testing Device and clarifies the Agency's compliance policy on the use of quantitative fit testing equipment by employers when encountered during OSHA inspections.

OSHA's standards for asbestos, benzene, formaldehyde, cadmium, methylenedianiline, and lead in construction contain a mandatory appendix that details specific requirements for quantitative fit testing (QNFT) instrumentation as well as QNFT protocols. Regarding instrumentation, these standards specifically require the use of aerosol generation, dilution and measurement systems that use photometer technology which measures the mass of particles leaked through the facepiece. Since the first promulgation of the QNFT requirements in the asbestos standard in 1986, the QNFT technology has changed and QNFT can be achieved with variations in technology and protocols. At least two QNFT devices are available in the marketplace that utilize variations in instrumentation and/or testing protocols to identify leaks in the respirator's face-to-facepiece seal.

In the Agency's view, the goal of QNFT is to detect leaks in the face-to-facepiece seal and to select the best fitting respirator facepiece for the worker. During inspections of workplaces with employee exposures to asbestos, benzene, formaldehyde, cadmium, methylenedianiline, and lead in construction, the compliance officer shall determine whether the employer has implemented quantitative fit testing as required by the standard. If the employer has failed to implement QNFT, a violation exists and it is to be cited.

However, as you know since 1988, we have permitted the use of the Portacount fit test device to be considered as a de minimis violation. The Portacount is the ambient particulate measurement instrument that compares ambient air particulate matter concentration inside and outside a respirator facepiece, utilizing condensation nuclei counting technology. The ambient particulate measurement device has undergone testing which has suggested it to be reliable. More recently we have been asked to

grant the same consideration to the FitTester 3000, the controlled negative pressure (CNP) device, which is based on a totally different principle.

The issue of what types of fit testing to permit and how to determine their validity is becoming more complex than in the past, and it is intended that it will be addressed in detail in the coming proposal to revise the respiratory protection standard later this year. In that proposal, a suggested set of criteria for evaluation of new types of fit testing and their validation will be presented and will be explored throughout the rule-making. Docket #H049 is now open and we expect voluminous comments when the proposal is published in the Federal Register. Hearings will be held as well.

During the interim period before the final rule is promulgated, we will continue the policy of considering the ambient particulate measurement device as a de minimis violation. In addition, during this period we will also accord the same treatment to the controlled negative pressure method on the basis of test results that have been presented by the manufacturer.

In OSHA's view, exercises are important elements of the QNFT protocol to detect leaks in the face-to-facepiece seal. Even though the ambient particulate measurement and CNP devices vary from the specific instrument requirements of OSHA standards, we believe that a fit test protocol that includes a series of exercises, each of 1 minute duration, must be conducted. An employer who uses either the ambient particulate measurement or CNP device and a fit test protocol that includes an exercise regimen of one-minute exercises to detect leaks in the respirator's face-to-facepiece seal provides similar protection and will be in substantial compliance with the QNFT requirements of the specific OSHA standards.

If, during inspections of workplaces with employee exposures to asbestos, benzene, formaldehyde, cadmium, methylenedianiline, and lead in construction, an employer is found to be conducting quantitative fit testing with ambient particulate measurement or CNP devices, using a QNFT protocol that includes one-minute exercises, the violation shall be noted as de minimis.

During this period and until the final revised respiratory protection standard is issued, we will not consider any other QNFT device for equivalent acceptance. During the course of the rulemaking, the ambient particulate measurement and CNP methods as well as other possible QNFT methods will be examined and re-evaluated with the objective of establishing a realistic program for the evaluation of fit test methods and, in particular, new fit test technology.

Should you have any questions concerning this compliance matter, please contact the Office of Health Compliance Assistance.

U. S. DEPARTMENT OF LABOR
OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION
Salt Lake Technical Center
1781 South 300 West P.O. Box 65200
Salt Lake City, UT 84165-0500

DRAFT

487-0521
FAX: 487-1180
Area Code: 801

DATE: October 21, 1993

MEMO FOR: ROGER CLARK. DIRECTOR
DIRECTORATE OF COMPLIANCE PROGRAMS

FROM: PATRICIA CLARK, DIRECTOR
DIRECTORATE OF TECHNICAL SUPPORT

SUBJECT: DYNATECH NEVADA FIT TEST3000 UNIT

After reviewing data on the subject instrument and interviewing several concerned parties, we conclude that current information supports its suitability for use in respirator fit testing assuming it is used within the manufacturer's recommended guidelines under which the conservative fit test results have been obtained. We suggest the following wording for a memorandum to the Regional Administrators on this instrument. If you have any questions, please contact Bob Curtis or Keith Motley of my staff at 801-487-0521.

Several letters of inquiry concerning the acceptability of the Dynatech Nevada Corporation's controlled negative pressure instrument for quantitative fit testing (QNFT) of respirators have recently been received. This is to clarify the Agency's compliance policy on the use of this equipment by employers if encountered during the course of an OSHA inspection.

Several OSHA standards specifically require the use of aerosol-generation, dilution and measurement systems that utilize photometer technology which measures the mass of particles leaked through the facepiece. The controlled negative pressure instrument measures the leakage rate of air into a respirator mask which has the interior pressure being held constant by the subject holding their breath. The leakage rate is then correlated to a fit factor. As such, the two instruments represent entirely different measuring techniques. Therefore, until such time as a change or correction to the standards that require a specific QNFT protocol to be followed can be made and published, any use of the Dynatech Nevada Corporation instrument for QNFT under a standard that specifies the aerosol generation system is, technically, a violation of that standard.

Recently, however, the Directorate of Technical Support

DRAFT

has reviewed several studies which indicate that while different technologies are being utilized, the CNP instrument reports more conservative fit factors than the aerosol counting instruments. The use of this type of device instead of the specific instrumentation mandated in currently existing fit test protocols therefore poses no direct or immediate relation-ship to employee safety or health. Thus, if an employer is utilizing the Dynatech Nevada unit to fit test respirators under the manufacturers recommended guidelines which were used in the validation studies, a de-minimus violation of the applicable standard would exist.

Additional questions concerning compliance issues may be addressed to Ruth McCully, Office of Health Compliance Assistance, (FTS) 202-219-8036. Technical equipment questions and information on respirator testing devices should be address to the Directorate of Technical Support.

M/R: Dynatech Nevada Controlled Negative Fit-Test Unit

DTS/SLTC/HRT/KMotley/revised by rc 21 Oct 1993
Filename: M:\mtos\pp4hp01.km

Nov 8, 1988

MEMORANDUM FOR: REGIONAL ADMINISTRATORS

THROUGH: LEO CAREY, DIRECTOR
OFFICE OF FIELD PROGRAMS

FROM: THOMAS J. SHEPICH, DIRECTOR
DIRECTORATE OF COMPLIANCE PROGRAMS

EDWARD BAIER, DIRECTOR
DIRECTORATE OF TECHNICAL SUPPORT

SUBJECT: Portacount Fit Testing Device

Several letters of interpretation and memoranda concerning the acceptability of the TSI Portacount Portable Fit Testing Device for quantitative fit testing (QNFT) of respirators have recently been distributed to your attention (see attached). This is to clarify the Agency's compliance policy on the use of this equipment by employers if encountered during the course of an OSHA inspection.

Several OSHA standards specifically require the use of aerosol-generation, dilution and measurement systems that utilize photometer technology which measures the mass of particles leaked through the facepiece (OSHA uses the Dynatech-Frontier units to quantitatively fit test our own employees). The TSI Portacount is an instrument that compares ambient air particulate matter concentration inside and outside a respirator facepiece, utilizing condensation nuclei counting technology. As such, the two instruments represent entirely different measuring techniques. Therefore, until such time as a change or correction to the standards that require a specific QNFT protocol to be followed can be made and published, any use of the Portacount for NFT under a standard that specifies the aerosol generation system is, technically, a violation of that standard.

Recently, however, the Directorate of Technical Support has contracted with the Lawrence Livermore National Laboratory to evaluate the performance of the Portacount device. Attached as "Attachment A" to this memo is a statement from Technical Support that discusses OSHA's evaluation of the Portacount unit's performance and provides additional technical information on its use and limitations. Based on this evaluation, the Agency feels that the Portacount unit is acceptable to use for respirator fit testing measurements. The use of this type of device instead of the specific instrumentation mandated in currently existing fit test protocols therefore poses no direct or immediate

relation-ship to employee safety or health. Thus, if an employer is utilizing the Portacount unit to fit test respirators that are approved for use when fit factors of less than 1,000 are required and the one-minute in-mask sampling correction has been made, a de minimus violation of the applicable standard would exist.

Additional questions concerning compliance issues may be addressed to Melody Sands, Office of Health Compliance Assistance, (FTS) 523-8036. Technical equipment questions and information on respirator testing devices should be address to the Directorate of Technical Support.

Attachments

cc: Health Standards Programs

FOREWORD

(This Forward is not part of American National Standard, RESPIRATOR FIT METHODS, ANSI Z88.10, 1989.)

This ANSI Z88.10 standard contains generic fit test methodology to use in conducting respirator fit testing and interpreting data. The committee has based this standard on the best available information. It outlines the procedures to use in validating qualitative fit testing protocols. Specific test protocols (two) are in Appendix A. A generic quantitative fit test is in Appendix B. This standard also covers the necessary training of personnel to conduct, participate in, and document a fit test.

This standard is processed and approved for submittal to ANSI by American National Standards Committee on Safety Standards for Respiratory Protection, Z88. Committee approval of this standard does not necessarily imply that all committee members voted for its approval. At the time it approved this standard, the Z88 committee had the following members:

(list of Z88 Committee Members as of January 1, 1989)

This standard was prepared by a subcommittee which had the following membership.

Darell	A.	Bevis	
Ching-tsen		Bien	
David	W.	Crosby	
Stephen	W.	Dixon	
Stephen	C.	Graham	
Alan	L.	Hack	
John	P.	Hale	
Lynnette		Hendricks	
Frank	J.	Lotito	
Doane	E.	Lucio	
Barry	C.	McNeill	(Chairman)
Gary	P.	Noonan *	
Tracy	W.	Parsons	
John	P.	Taylor	
Jeff	B.	Weed	
Jeff	M.	Wilson	

* (NIOSH nonvoting Technical Advisor)

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1. INTRODUCTION

1.1 SCOPE

This standard provides guidance on standard methods of performing respirator fit tests. The areas of qualitative and quantitative fit testing are covered in a generic manner. It is written so as not to restrict the future development of fit test equipment or test protocols.

1.2 PURPOSE

The purpose of this standard is to create uniform guidelines for qualitative and quantitative respirator fit testing and data interpretation. ANSI Z88.2 1990 must be consulted for other considerations about established respirator fit criteria and practices for respiratory protection.

1.3 REASON FOR FIT TESTING

Because faces show wide variation in size and shape, the ability of a respirator to form a satisfactory seal to the face must be determined in some way. A fit test is used to assess whether a given type, model and size of a respirator can adequately fit the wearer, thereby forming a satisfactory seal or barrier between the wearer and the contaminated atmosphere outside. There may be excessive leakage of contaminants into the wearer's breathing zone if the respirator fit is not adequate. This may occur even though a respirator correctly selected for the application is being worn. If an individual passes a fit test, the respirator still may not seal during use if the respirator is not properly used or maintained.

1.4 TYPES OF FIT TESTS

There are two basic types of fit tests: (1) qualitative and (2) quantitative. The qualitative test is a pass/fail test relying on the test subject's voluntary or involuntary response; i.e., taste, smell, or irritation, to a challenge. Any detection of the challenge by the wearer is considered a failure of the qualitative fit test.

A quantitative test uses instrumentation to measure the challenge leakage into the respirator without dependance on a test subject's voluntary or involuntary response to the challenge. The result can be expressed as a Fit Factor (FF).

You must distinguish qualitative and quantitative fit tests from "fit checks", such as the negative and positive pressure checks. These checks are performed by the wearer upon donning the respirator before each use.

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1.5 UNCERTAINTIES WITH APPLICATION OF FIT TESTS RESULTS

Uncertainty exists in predicting, solely by fit testing data, respirator performance in the workplace. This uncertainty results from such factors as; variability in fit between donnings of the respirator (from differences in positioning the respirator on the face or differences in strap tensioning), from variability and error in the fit test methods, and from variability due to conditions in the fit test that might not be representative of conditions of use. These variable conditions could be: physical movements by the wearer, workplace environmental factors, workrates, and the like. For these reasons the Required Fit Factor (RFF) used for fit testing is always higher than the Assigned Protection Factor (APF) of the respirator. See Z88.2 1990 for current Required Fit Factors. This uncertainty also limits the comparison of fit factors for determining the "best" fitting respirator. If the results of respirator fit tests show that the person can get the required fit factor with two or more respirators, they should be permitted to use the preferred respirator model.

1.6 SHALL and SHOULD

The provisions of this standard are mandatory in nature where the word *shall* is used. It is advisory in nature where the word should is used.

MAR 31 '95 12:41PM MOLDEX METRIC P.5

2. DEFINITIONS

AEROSOL - Particles, solid or liquid, suspended in air.

AIRLINE RESPIRATOR - An atmosphere supplying respirator in which the respirable gas source is not designed to be carried by the wearer (formerly called Air Supplied respirators).

AIR-PURIFYING RESPIRATOR - A respirator in which ambient air is passed through an air-purifying element which removes the contaminant(s). Air is passed through the air-purifying element by means of the breathing action or by a blower.

ASSIGNED PROTECTION FACTOR (APF) - The expected workplace level of respiratory protection that would be provided by a properly functioning respirator or a class of respirators to properly fitted and trained users.

ATMOSPHERE SUPPLYING RESPIRATOR - A respirator that supplies a respirable atmosphere independent of the workplace atmosphere.

CARTRIDGE/CANISTER - A container with a filter, sorbent, or catalyst, or combination, which removes specific contaminants from the air passed through it.

CHALLENGE - The substance or agents used as a test atmosphere to test respirator fit.

FILTER - A component used in respirators to remove solid or liquid aerosols from the inspired air.

FIT CHECK - A test conducted by the wearer to determine if the respirator is properly seated to the face.

FIT FACTOR -A quantitative measure of the fit or performance of a particular respirator on a particular individual. It is usually expressed as the ratio of challenge concentration outside the respirator to the concentration inside the respirator.

FIT TEST - The procedure to evaluate the fit of a respirator on an individual using a challenge. The outcome determines whether the required fit factor was met under a given set of physical conditions.

HELMET - A hood that provides physical head protection.

HIGH EFFICIENCY PARTICULATE AIR (HEPA) FILTER - A filter which removes from air 99.97% or more of aerosols having a diameter of 0.3 micrometers.

HOOD - A respiratory inlet covering that is not designed to form a seal with the wearer's face, and may cover the neck and shoulders.

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LOOSE FITTING FACEPIECE - A respiratory inlet covering that is designed to form a partial seal with the face and does not cover the neck and shoulders.

MOUTHPIECE - A respiratory inlet covering that is held in the wearer's mouth and is always be used with a nose clamp.

NEGATIVE PRESSURE RESPIRATOR - A respirator in which the air pressure inside the respiratory inlet covering is negative during inhalation with respect to the ambient air pressure.

POSITIVE PRESSURE RESPIRATOR - A respirator in which the pressure inside the respiratory inlet covering is normally positive with respect to the ambient air pressure.

QUALITATIVE FIT TEST - A pass/fail fit test that relies on the subject's sensory response to detect the challenge.

QUANTITATIVE FIT TEST - A fit test that uses an instrument to measure the challenge inside and outside the respirator.

REQUIRED FIT FACTOR - The minimum Fit Factor that must be attained to pass a fit test. (See ANSI Z88.2 1990 Section xx)

RESPIRATOR - A personal protective device designed to protect the wearer from the inhalation of hazardous atmospheres.

RESPIRATORY INLET COVERING - That portion of a respirator which connects the wearer's respiratory tract to an air-purifying device or respirable gas source, or both. It may be a facepiece, hood, suit or mouthpiece/nose clamp.

SENSITIVITY SCREENING TEST - A test done to be sure that the test subject can detect the qualitative challenge at sufficiently low levels to make the fit test valid.

SELF-CONTAINED BREATHING APPARATUS (SCBA) - An atmosphere supplying respirator in which the respirable gas source is designed to be carried by the wearer.

SENSITIVITY THRESHOLD - The minimum concentration of a challenge that can be detected by an individual.

SORBENT - A material contained in a canister/cartridge to remove specific gases and vapors from the inhaled air.

SUIT - A respiratory inlet covering designed to cover the entire body. It does not include protective clothing that only provides skin protection.

SUPPLIED AIR RESPIRATOR - See airline respirator.

TIGHT FITTING FACEPIECE - A respiratory inlet covering designed to form a complete seal with the wearer's face without forced respirable gas.

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WORKPLACE PROTECTION FACTOR (WPF) - A measure of protection provided in the workplace by a properly functioning respirator when correctly worn and used during normal work activities.

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3. OPERATOR TRAINING

Training enables the fit test equipment operator to conduct a complete test, including a determination of whether the test subject has obtained an adequate seal. Specifically the operator *shall* be able to do the following:

3.1 MAINTAIN THE EQUIPMENT

(1) Setup the equipment.

(2) Prepare the sensitivity screening and challenge materials for the qualitative fit test.

(3) Perform maintenance checks on the equipment, as appropriate, e.g. leak checks, filter replacement, replenish challenge materials for quantitative fit test.

(4) Prepare and maintain the respirators to be used in fit testing.

(5) Check the respirators for malfunctions.

3.2 PERFORM THE FIT TEST

(1) Explain the fit test purpose, procedure and test results to the test subject.

(2) Recognize and evaluate characteristics of the test subject which may affect the respirator seal: e.g., improper donning or fit check techniques, facial hair or irregularities, eyeglasses, other equipment worn on the head or face.

(3) Recognize behavioral characteristics likely to affect the fit test: e.g. lack of cooperation or evidence of claustrophobia. (See ANSI Z88.2 1990 for further discussion.)

(4) Refrain from coaching or aiding the test subject on donning technique or adjustment of the respirator during a fit test. The test subject *shall* don the respirator for the fit test in the same manner as for field use: i.e. with no coaching or help. It is acceptable to coach and help the test subject during training, but not during the fit test.

(5) Refrain from repeatedly fit testing the same respirator until an adequate fit is achieved. This refers to forcing a fit by the adjusting or redonning until a pass is achieved.

(6) Minimize exposure of the test subject and the operator to the challenge.

(7) For qualitative fit tests, conduct a sensitivity screening test.

(8) For quantitative fit tests, adhere to operating parameters important to a valid test.

(9) Recognize conditions that might invalidate the test; e.g., not following protocol, test subject's non-cooperation, sensitivity fatigue, and the like.

(10) Determine a pass or fail when conducting a fit test.

(11) Conduct a complete fit test including a determination of whether the fit test subject has obtained an adequate fit.

4. RESPIRATOR FIT TEST METHODS

4.1 PERFORMANCE REQUIREMENTS FOR RESPIRATOR FIT TESTS

The following performance requirements *shall* be incorporated into both qualitative and quantitative fit tests. Additional steps specific to qualitative or quantitative fit testing are specified in Sections 4.2 and 4.4 respectively.

(1) Before the test, the proper donning and operation of the respirator and the purpose and procedures for the fit test *shall* be explained to the test subject.

(2) The test subject *shall* wear the respirator for a familiarization period. This *shall* be at least five (5) minutes just before the test.

(3) Exercises *shall* be performed according to Section 5 for at least 30 seconds per exercise.

(4) Consideration *shall* be given to possible interferences with respirator fit by other safety equipment. If interferences are found then fit testing *shall* be performed with the other equipment, e.g., eyeglasses and goggles with halfmask respirators, hardhats with full facepieces, and the like.

(5) The respirator filter or sorbent elements (canister/cartridge) used *shall* be appropriate for the challenge. Where the filter cannot be changed, i.e., some disposable respirators, the challenge must be selected so that it can be stopped by the filter. The elements *shall* be efficient enough to allow determination of a fit factor of at least three (3) times the Required Fit Factor (RFF). In practice this means that HEPA filters are required for sub-micrometer aerosol tests and sorbent canister/cartridges are required for other tests, e.g., organic vapor for an isoamyl acetate test.

This may be expressed as:

$$E > 100 - \left[\frac{100}{(RFF \times 3)} \right]$$

Where:

E = element efficiency (percent)

RFF = Required Fit Factor

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(6) Challenge exposure limitations *shall* be considered for the test operator, especially during day long operation of the equipment. Challenge exposure *shall* be limited in accordance with current health guidelines where available, e.g., OSHA PEL or ACGIH TLV. The applicable time-weighted average dose; e.g., 8-hour, 15 minute (STEL), or ceiling limit *shall* be used in considering exposure and nonexposure time. The test subjects *shall* also be considered, but their exposure is likely to be lower due to the brief duration of the test and the protection provided by the respirator.

Any hazards of the challenge *shall* be communicated to both the operator and each test subject (e.g. Hazardous Communication Standard, 29 CFR 1910.1200).

(7) The oxygen concentration of the test atmosphere *shall* be maintained between 19.5% to 23.0%.

(8) For flammable challenges, the maximum concentration in the test enclosure *shall* not exceed 1/10 the lower explosive limit (LEL) in the highest expected oxygen concentration in which the facility is operated.

4.2 QUALITATIVE RESPIRATOR FIT TESTS

This section covers qualitative fit tests. Only validated qualitative fit test protocols *shall* be used.

4.2.1 Accepted Protocols

Two validated qualitative fit tests are (1) an odorous vapor test (isoamyl acetate) and (2) a taste test (saccharin). The protocols for these qualitative fit tests are given in Appendix A.

4.2.2 Design Requirements for New Qualitative Fit Tests

For a Qualitative Fit Test to be accepted, it *shall* meet the following minimum requirements.

(1) Meet the performance requirements in 4.1, applicable to all respirator fit tests.

(2) Meet the additional performance requirements in 4.2.3, applicable to qualitative fit tests.

(3) Meet the validation requirements in 4.3.

4.2.3 Performance Requirements for New Qualitative Fit Tests

These requirements *shall* be incorporated into qualitative fit tests. They *shall* be documented in a standard protocol which *shall* be closely followed.

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(1) A sensitivity screen *shall* be performed to ensure that the test subject can sense the challenge at the sensitivity threshold concentration before each fit test.

(2) A proper challenge *shall* be used which has a designed and fixed minimum challenge concentration per the following formula.

$$C_{out} = KC_{sen} \times RFF$$

Where:

K = empirical adjustment factor required to pass the validation in 4.3

C_{out} = required challenge concentration

C_{sen} = sensitivity threshold concentration

RFF = Required Fit Factor

The test concentration *shall* be controlled to plus or minus 25 percent (coefficient of variation of 0.25) of the design concentration. The control is for the duration of the test and repeatedly from test to test. This *shall* be demonstrated during test validation, but need not be measured for each test. For aerosol challenges, the mass media aerodynamic diameter should be < 5 micrometer.

4.3 VALIDATION OF NEW QUALITATIVE FIT TESTS

A new qualitative fit test method *shall* be validated before it is used. Once validated, the protocol need not be validated with each use or by every organization using the protocol. Once the protocol has been shown to be a valid method, it continues to be so as long as the protocol is followed.

Validation occurs in two phases. First, Qualitative Fit Tests conducted by the protocol are followed by Quantitative Fit Tests as in 4.3.1, or other quantitative methods of exposure or leakage testing. Second, the results of the Qualitative Fit Tests and Quantitative Fit Tests are statistically analyzed as in 4.3.2. Therefore, a Qualitative Fit Test protocol is valid if it meets the requirements of 4.2.2, 4.2.3, and 4.3.

4.3.1 Validation Using The Quantitative Fit Test Method

Validation consists of donning the respirator, conducting the qualitative fit test and then conducting a quantitative fit test. The facepiece fit must not be disturbed between the two tests. For each test pair, a pass or fail of the qualitative fit test and a quantitative fit test measurement are obtained. The range of measured quantitative fit factors should bracket the required fit factor.

Example: To validate a fit test with a Required Fit Factor of 100 (RFF=100), measured quantitative fit factors should be distributed above and below 100, with some values near 100.

4.3.2 Statistical Methods And Criteria For Fit Test Validation

The evaluation of the quantitative validation data *shall* confirm that the qualitative test protocol correctly passes people who meet the required fit factor (FF ≥ RFF). It also correctly fails people who do not meet the required fit factor (FF < RFF).

The validation *shall* show that the following criteria are met. Detailed guidance is given in Appendix A3.

(1) Test Sensitivity ≥ 0.95

(2) Predictive Value of a Pass ≥ 0.95

(3) Test Specificity > 0.5

(4) Predictive Value of a Fail > 0.5

In addition, preparation of a cumulative distribution plot, histogram, or other statistical procedure *shall* confirm visually that the quantitative Fit Factors bracket the Required Fit Factor.

Example: If all quantitative fit factors for qualitative fit test fails are between 1 and 5, and all quantitative fit factors for passes are greater than 1000 then the fit test may be incapable of discriminating between good and poor fits around a fit factor of 100, even though the nonparametric analysis results would meet the criteria.

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4.4 QUANTITATIVE FIT TEST

This section covers quantitative fit tests including minimum requirements, equipment components, and challenge necessary for a valid fit test. These elements normally would be developed by a manufacturer or systems designer. Once developed, it is not necessary for the person or organization using the Quantitative Fit Test to confirm the elements for each fit test provided that established protocols for fit testing and systems maintenance are followed. A generic procedure for an acceptable Quantitative Fit Test is presented in Appendix B.

4.4.1 Design Requirements

This section covers quantitative fit tests. Many quantitative fit test protocols and designs of equipment are available and can be used. The following basic requirements are established to provide for reproducibility of fit test results from test to test and equipment to equipment.

(1) Meet the performance requirements in 4.1, applicable to all respirator fit tests.

(2) Meet the additional performance requirements in 4.4.2, applicable to quantitative fit tests.

4.4.2 System Requirements

(1) The system *shall* quantify the challenge inside and outside over the period of the fit test with a coefficient of variation of 0.25, (± 25% at least 67% of the time). This does not include sampling error.

(2) The system *shall* measure a range of leakage from 100% down to at least the leakage equivalent to the RFF.

(3) The total system *shall* be calibrated, operated, and maintained in accordance with the manufacturer's instructions.

(4) In Mask Sample Collection Location

The sample collection point inside the respiratory inlet covering *shall* be located so as to collect a representative sample of atmosphere inside the facepiece. To minimize variation from mask-to-mask and face-to-face the sample location should be standardized on the wearer's face. This can be done by locating the collection point on the wearer's face between the mouth and nose, on the midline of the face (philtrum).

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(5) Challenge

(a) A controlled or measured challenge *shall* have a concentration of at least two (2) times the minimum detectable level times the RFF at a coefficient of variation of 0.125 (± 12.5% for 67% of the time) [$C_{Out} \geq 2$ MDL x RFF]

(b) The challenge concentration *shall* not vary by more than ± 25% during the fit test.

(c) The size distribution of aerosol challenges *shall* be:

<u>Mass sensitive systems</u>: *Shall* have no more than 25% of the mass of the measured aerosol greater than 2 micrometer aerodynamic diameter.

<u>Count sensitive systems</u>: *Shall* have not more than 25% of the measured aerosol count greater than 2 micrometer.

(6) Sampling Systems (where appropriate) *Shall* Include:

Sampling system: e.g., sample flow rate indicator, probe and transport tubing, which route a sample of the atmosphere inside the respirator to the challenge detector.

(a) The in-respirator sampling device *shall* not significantly change the fit of the respirator.

(b) The removal rate of the challenge sample inside the respirator *shall* not exceed four (4) lpm, unless it can be demonstrated that a higher sample rate will not disturb the normal operation of the respirator or the sample is returned to the respirator.

(c) The materials used in the sampling system *shall* not significantly absorb, deposit, or chemically react with the challenge.

(d) The sampling system flow path from the probe to the detector *shall* be as short, smooth, and continuous as possible to minimize substantial loss of challenge.

(e) The sampling rate chosen *shall* be appropriately monitored and controlled such that the flow rate does not vary by more than ± 10% during the time measurements are being taken.

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(7) Detector/ Signal Processor

(a) The instrument *shall* be spanned and zero checked, where appropriate, per the manufacturer's instructions.

(b) Interferences *shall* be identified and controlled or considered in determining the minimum detection limit, e.g., cigarette smoke in exhaled breath for condensation nuclei counters (cnc), alcohol in the breath for flame ionization detector (fid), and oxygen for electron capture detector.

(c) If an analog to digital converter is used the sampling frequency *shall* be 1 second or faster.

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5. EXERCISES FOR RESPIRATOR FIT TESTING

The following list of exercises are keyed to the different types of respiratory inlet coverings. The exercises listed in table 1 for tight fitting facepieces *shall* be the minimum used in fit testing those type respirators. Exercises for other types of devices (Table 2) are offered for guidance only. The use of other exercise regimens may be warranted by conditions of respirator use or test goals. ANSI Z88.2 1990 specifies tight fitting respirators *shall* be fit tested before field use.

In practice for example, the fit test for a SCBA would normally be conducted with only the respirator facepiece and in a negative pressure mode. Fit tests for entire SCBA ensembles are considered to be performance tests as they evaluate more than just the facepiece seal.

5.1 LIST OF EXERCISES:

NB Normal breathing

DB Deep breathing

SS Turning head from side-to-side, pausing at each end of travel for one breath's duration

UD Moving head up-and-down, pausing at each end of travel for one breath's duration

TK Talking, reciting the alphabet, or reading a prepared text

HR Holding a rod in both hands, slowly swing arms and torso from side-to-side, "Sandblaster's movements"

RO Reaching overhead with both hands

TT Bending over and touching toes with both hands

RP Running in place

SQ Squatting, short of a full deep knee bend

CR Crawling on hands and knees

ST Some stressful exercise to evaluate the breathing rate

---

* Exercises HR and RO may be combined

Normal breathing *shall* be required at the beginning and end of fit tests for all respiratory inlet coverings.

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TABLE 1

Physical Exercises For Tight Fitting Respiratory Inlet Coverings

Required or Optional	Exercises
Required	NB Normal breathing
Optional	DB Deep breathing
Required	SS Turning head from side-to-side, pausing at each end of travel for one breath's duration
Required	UD Moving head up-and-down, pausing at each end of travel for one breath's duration
Required	TK Talking, reciting the alphabet, or reading a prepared text
Optional *	HR Holding a rod in both hands, slowly swing arms and torso from side-to-side, "Sandblaster's movements"
Optional *	RO Reaching overhead with both hands.
Optional	BO Bending over and touching toes with both hands
Optional	RP Running in place
Optional	SQ Squatting, short of a full deep knee bend

* These exercises may be performed together as one exercise.

One of the optional exercises is required for the minimum exercise set.

These are the minimum exercises required for tight fitting facepieces, regardless of final mode of operation, whether air purifying or atmosphere supplying. The fit testing *shall* be done in the negative pressure mode.

Stressful exercises determine the ability of the respirator to provide protection during heavy exertion because it evaluates the total performance of the total system. The use of exercise machines permits a relatively stationary test subject to exercise up to stressful levels. A few examples are: the bicycle ergometer, treadmill, and laddermill (moving staircase).

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TABLE 2

Physical Exercises For Other Types of Respiratory Inlet Coverings

	Loose Fitting	Suit	SCBA	Mouth Piece
Normal Breathing	Suggested	Suggested	Suggested	Suggested
Deep Breathing	Suggested		Suggested	Suggested
Side to Side	Suggested	Suggested	Suggested	Suggested
Up & Down	Suggested	Suggested	Suggested	Suggested
Talk	Suggested		Suggested	
Hold Rod	Suggested	Suggested	Suggested	
Reach Overhead	Suggested	Suggested	Suggested	
Touch Toes	Suggested	Suggested	Suggested	
Run in Place			Suggested	Suggested
Squat		Suggested		
Crawl		Suggested	Suggested	
Stress Exercise			Suggested	Suggested

Stressful exercises determine the ability of the respirator to provide protection during heavy exertion because it evaluates the total performance of the entire system. The use of exercise machines permits a relatively stationary test subject to exercise up to stressful levels. A few examples are: the bicycle ergometer, treadmill, and laddermill (moving staircase).

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6. DATA REDUCTION AND INTERPRETATION

6.1 INTERPRETING QUALITATIVE FIT TEST RESULTS

The result of a qualitative test *shall* be recorded as either pass or fail. To pass, the test subject *shall* not have detected the challenge during any of the exercises. See Section 5 for details on the exercises.

6.2 INTERPRETING QUANTITATIVE FIT TEST RESULTS

A fit factor is a single number which tries to characterize the fit of a respirator (brand, model and size) on an individual under a given set of conditions. If quantitative fit tests on an individual are repeated many times, a range of fit factors will be obtained. The range of fit factor numbers is likely to be log normally distributed. Part of this variability results from differences in fit with different donnings and part is inherent to the Quantitative Fit Test system.

The result of a Quantitative Fit Test *shall* be reported as a fit factor in addition to a pass or fail. To pass, a fit factor greater than or equal to the Required Fit Factor (RFF) must be achieved. In all cases the fit factor *shall* be based on the complete series of required exercises, and if used, all supplementary exercises. See Section 5 for details on exercises. One of the following methods of fit factor determination will be applicable depending on the type of Quantitative Fit Test system used:

6.2.1 Fit Factor By Simultaneous Measurement

By simultaneously measuring the average challenge concentration outside and inside the respirator during the entire exercise sequence and then applying the following formula:

$$\text{Fit Factor} = \left[\frac{C_{out}}{C_{in}} \right]$$

Where: C_{out} = The average challenge concentration outside the respirator during the entire exercise sequence

C_{in} = The average challenge concentration inside the respirator during the entire exercise sequence

6.2.2 Fit Factor By Average Concentration Over Exercise Set

Where C_{in} is expressed as the average concentration over the entire exercise set. This is done by measuring the ambient concentration before the exercises, then measuring the concentration inside the respirator during the exercises, and then measuring the ambient concentration again to compute an average ambient concentration. It is demonstrated that the challenge concentration does not vary by more than 10% during the duration of a test then it is not necessary to use the final challenge concentration calculating the Fit Factor.

Use the following formula:

$$\text{Fit Factor} = \frac{\left[\dfrac{C_{out}(i) + C_{out}(f)}{2}\right]}{C_{in}}$$

Where:

$C_{out}(i)$ = The initial outside concentration before the exercises

$C_{out}(f)$ = The final outside concentration after the exercises are completed

C_{in} = The average challenge concentration inside the respirator during the entire exercise sequence

6.2.3 Fit Factor By Percent Penetration Simultaneous Measurement

By measuring the percent penetration into the respirator for each exercise using simultaneous inside and outside measurements and applying the following formula:

$$\text{Fit Factor} = \left[\frac{N \times 100}{p_1 + p_2 + p_3 + p_4 \ldots + p_N}\right]$$

Where:

N = The number of exercises

p_1 = The percent penetration for the first exercise

p_2 = The percent penetration for the second exercise

p_3 = The percent penetration for the third exercise

p_4 = The percent penetration for the fourth exercise

p_N = The percent penetration for the Nth exercise

EXAMPLE:

Given the following percent penetration for a series of six exercises

$N = 6$

$p_1 = .15$

$p_2 = .07$

$p_3 = .17$

$p_4 = .05$

$p_5 = .09$

$p_6 = .11$

$$\text{Fit Factor} = \frac{6 \times 100}{.15 + .07 + .17 + .05 + .09 + .11} = 937$$

6.2.4 Fit Factor By Percent Penetration For Each Exercise

By measuring the ambient concentration before the exercises, then measuring the percent penetration for each exercise, and then measuring the ambient concentration again to determine the average ambient concentration. Use the following formula:

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$$\text{Fit Factor} = \frac{\left[\dfrac{A_i + A_f}{2}\right]}{\left[\dfrac{p_1 + p_2 + p_3 + p_4 \ldots + p_N}{N}\right]}$$

Where:

A_i = 100 (the initial ambient concentration is defined as 100%)

A_f = The final ambient concentration after the exercises are complete expressed as a percentage of A_i

N = The number of exercises

p_1 = The percent penetration for the first exercise

p_2 = The percent penetration for the second exercise

p_3 = The percent penetration for the third exercise

p_4 = The percent penetration for the fourth exercise

p_N = The percent penetration for the Nth exercise

Example:

Given the following data for a series of six exercises:

A_i = 100

A_f = 96

N = 6

p_1 = .06

p_2 = .17

p_3 = .08

p_4 = 1.1

p_5 = .12

p_6 = .025

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$$\text{Fit Factor} = \frac{\left[\dfrac{100 + 96}{2}\right]}{\left[\dfrac{.06 + .17 + .08 + 1.1 + .12 + .025}{6}\right]}$$

$$= \frac{98.000}{00.259} = 378$$

6.2.5 Fit Factor By Each Exercise

By measuring the fit factor for each exercise separately using the formula in Section 6.2.2 and applying the following formula:

$$\text{Fit Factor} = \frac{N}{\left[\dfrac{1}{FF_1} + \dfrac{1}{FF_2} + \dfrac{1}{FF_3} + \dfrac{1}{FF_4} \ldots + \dfrac{1}{FF_N}\right]}$$

Where:

N = The number of exercises

FF_1 = The fit factor for the first exercise

FF_2 = The fit factor for the second exercise

FF_3 = The fit factor for the third exercise

FF_4 = The fit factor for the fourth exercise

FF_N = The fit factor for the Nth exercise

Example:

Given the following fit factors for a series of six exercises:

$N = 6$

$FF_1 = 666$

$FF_2 = 1429$

$FF_3 = 588$

$FF_4 = 2000$

$FF_5 = 1111$

$FF_6 = 909$

Fit Factor =

$$\frac{6}{\left[\frac{1}{666} + \frac{1}{1429} + \frac{1}{588} + \frac{1}{2000} + \frac{1}{1111} + \frac{1}{909}\right]} = 937$$

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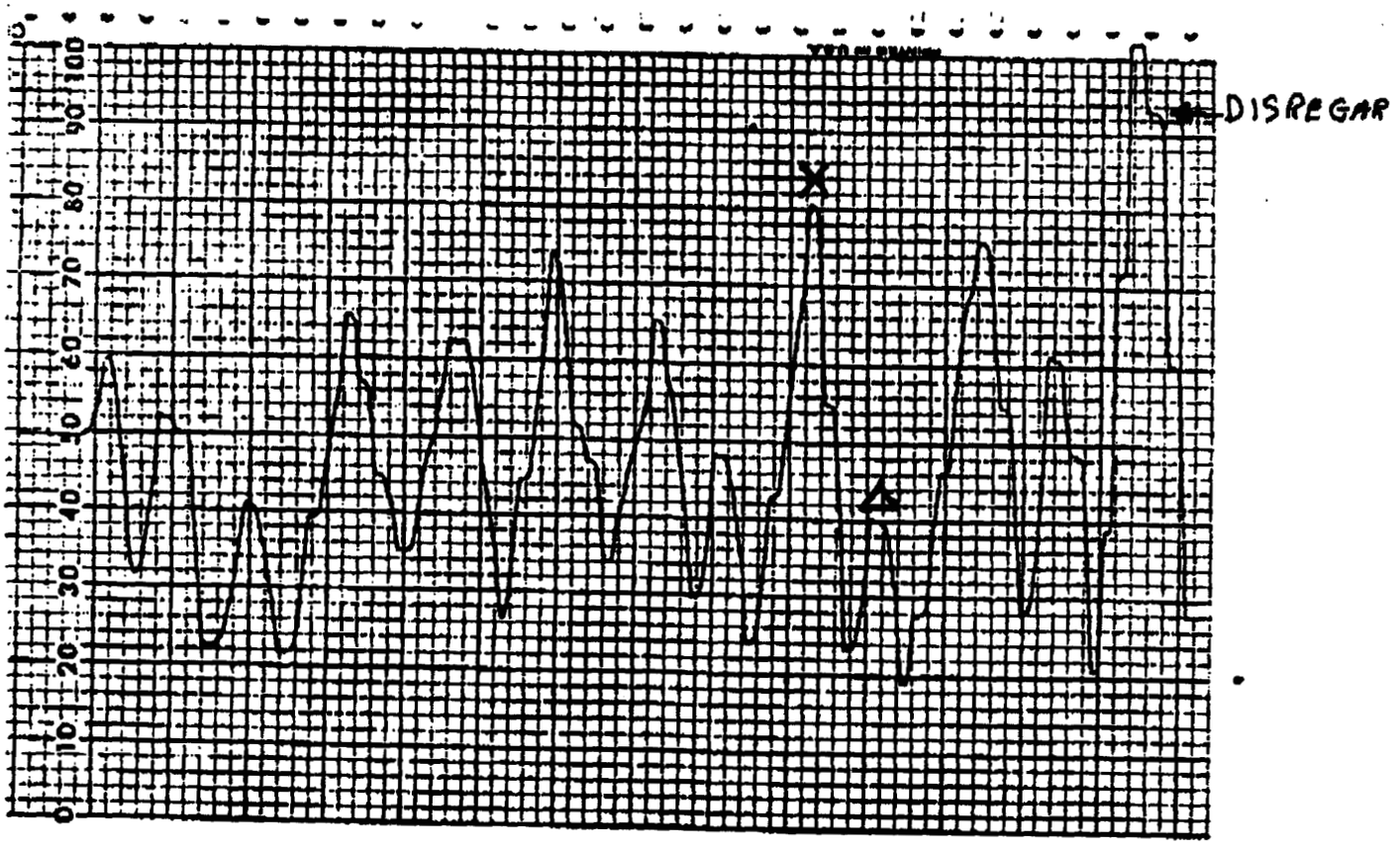
9.3 INTERPRETING ANALOG STRIP CHART RECORDER READINGS

There are two types of analog strip charts, logarithmic and linear. The penetration into the wearers mask by the challenge is recorded on the chart and used to determine the fit factor for the exercise. This percent penetration reading *shall* be interpreted by the "high peak average" method. This is accomplished by adding the high peak reading and the low peak reading together and dividing the result by 2. Excessive or spurious peaks are to be disregarded.

Example: See the example copy of a strip Chart below.



X = high peak reading = 80
♦ = low peak reading = 40 TOTAL 120/2 = 60

"High Peak Average" equals 60

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7. RECORDKEEPING

Respirator fit test and protocol records *shall* be kept for the time and manner consistent with current legal requirements and organizational policy.

Fit test records *shall* include, as a minimum, the items listed in 7.2 and 7.3.

7.1 VALIDATION DOCUMENTATION OF QUALITATIVE FIT TEST PROTOCOLS

Written records *shall* be kept on experimental methods, sensitivity and challenge concentration determinations, pass/fail paired Quantitative Fit Tests and other pertinent information. Publication in PEER reviewed journals is recommended.

7.2 FIT TEST OPERATOR TRAINING

Written records of operator training must be maintained. As a minimum, the training records *shall* consist of the name, date(s), training content, and form of instruction (current and on file). See Section 3, "Training" for further discussion of training requirements.

7.3 FIT TESTING

7.3.1 Program Records

(1) Test instrument maintenance, repair, and calibration.

(2) Test system, equipment operating procedures.

(3) Written standard operating procedures for the respirator fit testing program, including pass/fail criteria.

7.3.2 Records For Each Test

(1) Test instrumentation and equipment used.

(2) Type of respirator fit test(s) used, including specific fit test protocol.

(3) Name or identification of the test operator.

(4) Name or identification of the person tested.

(5) Date of fit test.

(6) Specific make, model, size, and composition (i.e. neoprene) of the respirator fit tested.

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(7) Fit factor based upon quantitative fit tests(s), the required RFF and success or failure to get a satisfactory fit test(s) from either a Qualitative Fit Test or Quantitative Fit Test.

(8) Other related safety equipment worn during test(s); e.g., hard hat, eye wear, and the like.

(9) Any special considerations or difficulties pertinent to the test subject; e.g., dentures, facial scars, hair interference, claustrophobic reactions, and the like.

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THESE APPENDIXES ARE NOT PART OF THIS ANSI Z88.10 AMERICAN NATIONAL STANDARD,

BUT ARE INCLUDED FOR INFORMATION ONLY.

They contain accepted protocols for performing Qualitative respirator fit tests and offer a generic outline for the Quantitative fit test equipment usage. Also offered is useful information for any respirator fit test program.

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QUALITATIVE FIT TEST VALIDATED PROTOCOLS

This appendix gives two qualitative fit test protocols that were validated to a Required Fit Factor (RFF) of 100. Full Face and Halfmask respirators which pass these tests can only be used up to an Assigned Protection Factor (APF) of 10.

A1. ISOAMYL ACETATE PROTOCOL

This protocol is suitable for performing fit tests using organic vapor sorbent equipped air purifying respirators.

A1.1 ODOR SENSITIVITY SCREENING

A1.1.1 Three 1-liter glass jars with metal lids; e.g., Mason or Ball canning jars, are required.

A1.1.2 Odor-free water; e.g., distilled or spring water, at about 25°C (± .8°C) must be used for the solutions.

A1.1.3 The Isoamyl Acetate (IAA) (also known as isopentyl acetate) stock solution is prepared by adding 1 ml of pure IAA to 800 ml of odor free water in a 1-liter jar and shaking for 30 seconds. The solution must be prepared new at least weekly.

A1.1.4 The sensitivity screening test must be conducted in a room separate from the room used for actual fit testing to prevent odor build up. The mixtures used in the IAA odor sensitivity screening test must be prepared in an area separate from where the test is performed to prevent olfactory fatigue in the subject.

A1.1.5 The odor screening solution is prepared in a second jar by placing 0.4 to 0.5 ml of the stock solution into 500 ml of odor free water using a clean dropper or pipette. Shake for 30 seconds and allow to stand for two to three minutes so the IAA concentration above the liquid may reach equilibrium. This solution may be used for only one day.

A1.1.6 A screening blank is prepared by filling a third jar with 500 ml of odor free water.

A1.1.7 The odor screening and blank screening jars must be labelled, e.g., 1 and 2, for jar identification.

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A1.1.8 The following instructions should be on a card and placed on the table in front of the two test jars; i.e., 1 and 2:

"The purpose of this test is to determine if you can smell 'banana oil' at a low concentration. Two jars in front of you contain water. One of these jars also contains a small amount of 'banana oil'. Be sure the covers are on tight, then shake each jar for two seconds. Unscrew the lid of each jar, one at a time, and sniff at the mouth of the jar. Indicate to the test conductor which jar contains banana oil."

A1.1.9 If the test subject is unable to identify correctly the jar containing the odor screening solution, the IAA Qualitative Fit Test may not be used.

A1.1.10 If the test subject correctly identifies the jar containing the odor screening solution, the test may continue to respirator selection and fit testing.

A1.2 RESPIRATOR SELECTION

A1.2.1 The test subject should be allowed to select the most comfortable respirator from different sizes and brands of facepieces.

A1.2.2 The selection process must be conducted in a room separate from the fit-test chamber to prevent odor fatigue. Before the selection process, the test subject must be shown how to put on a respirator, how to position it on the face, how to set strap tension and how to assess a comfortable respirator. A mirror must be available to aid the subject in evaluating the fit and positioning of the respirator.

A1.2.3 The test subject should understand that the individual is being asked to select the respirator which provides the most comfortable fit. Each respirator represents a different size and shape and, if fit properly, will provide adequate protection.

A1.2.4 The test subject should hold each facepiece up to his face and eliminate those which are obviously not giving a comfortable fit.

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A1.2.5 The comfortable facepieces should be recorded, the most comfortable mask is donned and worn at least five (5) minutes to assess comfort. Help in assessing comfort can be given by discussing the points in A1.2.7 below. If the test subject is not familiar with using a particular respirator, direction must be given to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

A1.2.6 The test subject must conduct the proper fit checks. Before conducting the fit checks, the subject must be told to seat the mask by rapidly moving the head side-to-side and up-and-down, taking a few deep breaths.

A1.2.7 Assessment of comfort should include reviewing the following points with the test subject:

(1) Chin properly placed

(2) Positioning of mask on nose

(3) Strap tension

(4) Fit across nose bridge

(5) Room for appropriate eye wear

(6) Distance from nose to chin

(7) Room to talk

(8) Tendency to slip

(9) Cheeks filled out

(10) Self-observation in mirror

A1.2.8 The test subject is now ready for fit testing.

A1.2.9 After passing the fit test, the test subject must be questioned about the comfort of the respirator. If it has become uncomfortable, another model of respirator must be tried.

A1.3 FIT TEST

A1.3.1 The fit test chamber must be similar to a transparent 55 gallon drum liner suspended inverted over a 0.6 meter (2 foot) diameter frame, so the top of chamber is about 15.24 cm (6 inches) above the test subject's head. The inside top center of the chamber must have a small hook attached.

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A1.3.2 Each respirator used for the fitting and fit testing must be equipped with organic vapor canister/cartridges or offer protection against organic vapors.

A1.3.3 After selecting, donning, and properly adjusting a respirator himself, the test subject must wear it to the fit testing room. This room must be separate from the room used for odor threshold screening and respirator selection, and must be well ventilated, by an exhaust fan or lab hood or other means, to prevent general room contamination.

A1.3.4 A copy of the following test exercises and rainbow or other passage should be available for view by the subject inside the test chamber:

(1) Normal breathing.

(2) Deep breathing.

(3) Turning head from side-to-side, stopping at the end of each travel for 1-2 breaths.

(4) Move head up-and-down, holding it at each end for 1-2 breaths.

(5) Talking. Recite the alphabet or read a prepared text. The following paragraph is called the Rainbow Passage. Reading it will result in a wide range of facial movements, and thus be useful to satisfy this requirement. Alternative passages which serve the same purpose may also be used.

Rainbow Passage
"When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow".

(6) Normal breathing.

A1.3.5 Each test subject must wear his respirator for at least 5 minutes before starting the fit test.

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A1.3.6 Upon entering the test chamber, the test subject must be given an unused 15.25 cm (6") by 12.7 cm (5") piece of paper towel or other porous absorbent single ply material, folded in half and wetted with 0.5 of one ml of pure IAA. The test subject must hang the wet towel on the hook at the top of the chamber.

A1.3.7 Allow two minutes for the IAA test concentration to be reached before starting the fit-test exercises. This would be a suitable time to talk with the test subject and explain the fit test. Some of the topics covered should be the importance of test subject's cooperation, the purpose for the head exercises, and showing of the exercises.

A1.3.8 Each exercise described in A1.3.4 above must be performed for thirty (30) to sixty (60) seconds.

A1.3.9 If at any time during the test, the subject detects the banana-like odor of IAA, he must quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

A1.3.10 Upon returning to the selection room, the subject must remove the respirator and repeat the protocol beginning with the sensitivity screening. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject must wait about 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

A1.3.11 When the test subject leaves the chamber he must remove the saturated towel, returning it to the test conductor for disposal. The used towels must be kept in a sealed container to keep the surrounding area from becoming contaminated.

A1.3.12 If the entire test is completed without the subject detecting the odor of the IAA, the test is passed and the respirator's fit on that individual is judged as adequate. The respirator may be used with an assigned protection factor of ten (10), as a Required Fit Factor of 100 has been attained in this test.

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A2. SACCHARIN AEROSOL PROTOCOL

This protocol is suitable for performing fit tests using respirators equipped with particulate filters. Full Face and Halfmask respirators which pass this test can only be used up to an Assigned Protection Factor (APF) of 10.

A2.1 MATERIALS

(1) Two DeVilbiss Model 45 Inhalation Medication Nebulizers.

(2) Sodium saccharin, USP grade.

(3) Two measuring devices suitable for 1 ml and 100 ml delivery.

(4) An enclosure, 30.48 cm (12") diameter x 35.6 cm (14") tall, with clear front or window to view test subject. The enclosure must have some structural means of maintaining these dimensions during the test to allow for even dispersion of the aerosol in the area where the respirator seals to the subject's face. A 1.9 cm (3/4") diameter hole should be made in the enclosure about at the level of the subject's mouth for insertion of the nebulizer nozzle.

(5) A mirror.

A2.2 TEST SOLUTION PREPARATION

(1) Fit Test Solution: add 83 grams of sodium saccharin to 100 ml of warm water (helps the saccharin dissolve). Mix well. Label the solution container **Fit Test Solution.**

(2) Threshold Screening Solution: add 1 ml of the fit test solution to 100 ml of water. Label the container of this solution **Threshold Screening Solution.**

(3) Label first nebulizer **Fit Test.** Label second nebulizer **Threshold Screening.**

(4) Pour a small amount, about one teaspoonful of the threshold screening solution into the nebulizer labeled **Threshold Screening.** Pour about one teaspoonful of the fit test solution into the second nebulizer labeled **Fit Test.**

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A2.3 TASTE SENSITIVITY SCREENING

Purpose: This test is done to ensure that the person being fit tested can detect the taste of saccharin at sufficiently low levels to make the fit test valid. The threshold screening solution is a 100-to-1 dilution of the fit test solution.

(1) Ensure that the test subject does not eat, drink, or chew gum for 15 minutes before the test.

(2) Explain the screening and fit testing procedures to the subject.

(3) Have the subject put on the enclosure <u>without</u> a respirator.

(4) Position the hood (enclosure) forward so there is about six inches between the subject's face and the enclosure. This is especially important for the following fit test. It allows free movement of the head when the subject is wearing a respirator and helps ensure even dispersion of the aerosol around the face seal area.

(5) Instruct the test subject to breathe through their mouth.

(6) Using the nebulizer labeled **Threshold Screening**, inject the aerosol into the hood through the hole in the front of the enclosure. Inject ten squeezes of the bulb, fully collapsing and fully expanding the bulb on each squeeze.

(7) Ask the subject if he can detect the sweet taste of the solution.

(8) If the subject does not detect the sweet taste, inject an additional ten squeezes into the hood.

(9) If the subject still does not detect the sweet taste, inject an additional ten squeezes; i.e., to a total of 30 squeezes.

(10) If 30 squeezes were inadequate to elicit a response from the subject, this subject cannot be fit tested with the saccharin test. Another fit test method must be used.

(11) If the subject could detect the sweet taste, the number of squeezes required to produce a taste response should be noted; i.e., 10, 20, or 30 squeezes.

(12) Remove the hood. Wait a few minutes before proceeding to the fit test to give the subject time to clear the taste from his mouth. A drink of water during this time will aid in removing the sweet taste.

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A2.4 FIT TEST

(1) The respirator being tested on the subject must have a particulate filter. The filter could be one of the following: dust/mist, dust/mist/fume, high efficiency, paint, lacquer, enamel mist, or pesticide. Have the test subject put on and adjust the respirator per the instructions provided with the respirator. The subject may find a mirror useful in the adjustment process. The subject should wear the respirator at least five (5) minutes before starting the test.

(2) Have the subject put on and position the hood as before, See A. 2.3(4), and breathe through his mouth.

(3) Using the nebulizer labeled Fit Test, inject the fit test aerosol into the enclosure. The same number of squeezes are required as was necessary to elicit a response in the threshold sensitivity screening test: i.e., 10, 20 or 30 squeezes.

(4) To maintain an adequate concentration of aerosol during the test, one half of the initial number of squeezes should be injected again every 30 seconds.

(5) After injecting the aerosol initially, ask the test subject to perform the following exercises for 30 seconds each:

(a) Normal breathing.

(b) Deep breathing.

(c) Turning head from side to side, stopping at each end of travel for one or two breaths.

(d) Moving head up and down, holding at each end for one or two breaths.

(e) Talking, reciting the alphabet, or reading a prepared text.

(f) Normal breathing.

(6) Instruct the subject to indicate when he detects the sweet taste of saccharin.

(7) The test is stopped at the point the subject first detects the sweet taste of the aerosol. If this occurs, the fit of the respirator on the subject is judged inadequate.

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(8) If the test is failed, before retesting the subject a 15-minute waiting period must be observed and the threshold sensitivity screening test must be performed again.

(9) If the entire test is completed without the subject detecting the sweet taste of the aerosol, the test is passed and the respirator's fit on that individual is judged adequate. A Fit Factor of at least 100 has been attained with the use of this protocol.

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A3. STATISTICAL METHODS FOR QUALITATIVE FIT TEST VALIDATION

A3.1 GENERAL GUIDANCE

Validation studies are usually done in two phases to obtain enough "good" fits and "bad" fits for statistical evaluation.

A3.1.1 First, personnel who follow complete selection and fit check protocol are tested. They normally have "good" fits.

A3.1.2 Then, some personnel who follow a modified protocol are tested to obtain enough "bad" fits for the evaluation. They should not know whether a "bad" fit or a "good" fit is expected. Protocols may differ, but should incorporate the following guidelines:

(1) Respirators may be modified to artificially create leakage to generate necessary results for statistical analysis. The induced leakage must not be obvious to the test subject. Examples are testing of different sizes on the same individual, or induced exhaust valve leakage. Care must be taken that induced valve leaks are large enough to avoid aerosol challenge loses.

(2) A different test subject, however, is not necessary for each pair of tests. A variety of test subjects should participate, so person to person variability is included.

(3) Negative/Positive pressure fit checks should not be done, since they will clue test subjects on the fit.

A3.2 DATA COLLECTION

A minimum of 100 (most likely 150 - 200) paired quantitative and qualitative fit tests should be conducted including:

(1) At least 50 for which quantitative fit factors equal or exceed the required fit factor.

(2) At least 50 for which quantitative fit factors are less than the required fit factor.

(3) At least 50 for which the qualitative fit test was passed.

(4) At least 50 for which the qualitative fit test was failed.

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The results should then be grouped and statistically analyzed per Sections 3.2 through 3.5. These results provide useful insight into the performance of the fit tests.

A3.3 TEST SENSITIVITY (1 - BETA)

Of those who had quantitative fit factors less than "A" ("A" is the Required Fit Factor) what fraction failed the qualitative fit test? This fraction must be 0.95 (95%) or greater to ensure that those who have unacceptable fits will fail the fit test. This may be expressed as:

$$F_{<A} / (P_{<A} + F_{<A}) \geq 0.95$$

Where:

$P_{<A}$ = number passing fit test with quantitative fit factors less than the required fit factor.

$F_{<A}$ = number failing fit test with quantitative fit factors less than the required fit factor.

A3.4 PREDICTIVE VALUE OF A PASS

Of those who passed the qualitative fit test, what fraction had quantitative fit factors equal to or greater than the required fit factor? This fraction must be 0.95 (95%) or greater to ensure that those who pass the fit test will have acceptable fits. This may be expressed as:

$$P_{\geq A} / (P_{\geq A} + P_{<A}) \geq 0.95$$

Where:

$P_{<A}$ = Number passing fit test with quantitative fit factors less than the required fit factor.

$P_{\geq A}$ = Number passing fit test with quantitative fit factors equal to or greater than the required fit factor.

A3.5 TEST SPECIFICITY (1 - ALPHA)

Of those who had quantitative fit factors equal to or greater than the required fit factor, what fraction passed the qualitative fit test? This fraction should be greater than 0.5 (50%) to ensure that most wearers with acceptable fits will pass the fit test. This may be expressed as:

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$$P_{\geq A} / (P_{\geq A} + F_{\geq A}) > 0.5$$

Where:

$P_{\geq A}$ = Number passing fit test with quantitative fit factors equal to or greater than the required fit factor.

$F_{\geq A}$ = Number failing fit test with quantitative fit factors equal to or greater than the required fit factor.

A3.6 PREDICTIVE VALUE OF A FAIL

Of those who failed the qualitative fit test, what fraction had quantitative fit factors less than the required fit factor? This fraction should be greater than 0.5 (50%) to ensure that most of those who fail actually have unacceptable fits. This may be expressed as:

$$F_{<A} / (F_{\geq A} + F_{<A}) > 0.5$$

Where:

$F_{\geq A}$ = Number failing fit test with quantitative fit factors equal to or greater than the required fit factor.

$F_{<A}$ = Number failing fit test with quantitative fit factors less than the required fit factor.

A3.7 DISTRIBUTION EVALUATION

This evaluation is useful to confirm that fit factors bracket the required fit factor as discussed in Section 4.3.2. It consists of constructing separate cumulative distribution plots or histograms of quantitative fit factors for qualitative fit test passes and fails. A visual observation of the spread of fit factors around the required fit factor will show whether it is adequately bracketed. This method is used in Nelson's 1984 isoamyl acetate fit test protocol development study.

A3.8 OTHER VALIDATION APPROACHES

Other approaches for quantitative validation of qualitative fit tests, including other statistical methods, may be used if they are capable of demonstrating that the criteria in Section 4.3.2 are satisfied.

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A3.9 EXAMPLE STATISTICAL EVALUATION

In the following example, three Qualitative Fit Tests were evaluated per the guidance in this section. The following results were obtained, with a goal of determining whether they were acceptable to confirm a Required Fit Factor of 100.

Test #1

For individuals who had fit factors less than 100, 1 passed and 80 failed

For individuals who had fit factors of 100 or more, 70 passed and 20 failed.

Test #2

For individuals who had fit factors less than 100, 30 passed and 60 failed.

For individuals who had fit factors of 100 or more, 80 passed and 2 failed.

Test #3

For individuals who had fit factors less than 100, 0 passed and 70 failed.

For individuals who had fit factors of 100 or more, 50 passed and 150 failed.

These tests are tabulated in Table A1 which reports evaluation results from validations of Qualitative Fit Test Protocols.

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TABLE A1

Summary Table
Quantitative Fit Test Validation Data

	Quantitative Fit Tests = 1 - 99			Quantitative Fit Tests = 100 or more		
Tests	Pass	Fail	Total	Pass	Fail	Total
# 1	1	80	81	70	20	90
# 2	30	60	90	80	2	82
# 3	0	70	70	50	150	200

Table A2

The Statistical Parameters are Thus:

Facemask Fit Test **********	Sensitvty Screen **********	Predict Val Pass **********	Test Specifcty **********	Predict Val Fail **********
# 1	80/81	70/71	70/90	80/100
# 2	60/90	80/110	80/82	60/62
# 3	70/70	50/50	50/200	70/220

And the conclusions of the evaluation would be:

TEST #1 - Acceptable

TEST #2 - Unacceptable (too lax) it passes people with inadequate fits

TEST #3 - Unacceptable (too Stringent) it fails people with adequate fits

QUANTITATIVE FIT TEST

BASIC PROCEDURE

This procedure is a step-by-step guide to help the novice operator perform a Quantitative Fit Test that uses a photometric type detection device. It is written to be generic in nature and to apply to all manufacturer's equipment or types of system; i.e., oil mist, gas type, condensation nuclei systems. It is a guide only and does not relieve the operator of any other requirements detailed in the Z88.10 Standard. This guide also assumes the operator has been properly trained on the Quantitative Fit Test equipment being used, as outlined in Z88.10.

B1.0 Following the manufacturer's instructions connect all components of the Quantitative Fit Test system together; i.e., Data Logger, Amplifiers, Detectors, Challenge Agent Generator, Test Chamber, and the like.

B2.0 Perform or have performed any maintenance requirements, if required, as dictated by the manufacturer of the equipment; e.g., initially fill challenge agent generator. If the system has been operating, then observe required daily, weekly, or monthly maintenance before start-up. Log all maintenance work per recordkeeping requirements.

B3.0 Start up system and allow a proper warm-up period, per manufacturer's instructions.

B4.0 Perform any preliminary adjustments required by manufacturer's instructions; i.e., adjust sample flow, generator pressure, dilution flow, span gas flow, and the like.

B5.0 Allow time for challenge agent concentration to become stabilized in test area or test chamber, per manufacturer's instructions.

B6.0 Enter all pertinent data of test subject into subject's record; i.e., name, model of respirator, facial scars, and the like, for each fit test.

B7.0 Verify test subject has worn respirator a minimum of five (5) minutes to assure proper seating and verify subject has performed positive or negative pressure fit check if applicable.

B8.0 Have test subject enter test chamber or area and see that they properly connect respirator sample line.

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