AIHA
The Essential Source

54-208

President
JEREMIAH LYNCH, CIH
American Industrial Hygiene Association
2700 Prosperity Ave., Suite 250
Fairfax, VA 22031-4307
(703) 849-8888
(703) 207-3561 fax

President-Elect
VERNON E. ROSE, DrPH, CIH
University of Alabama
School of Public Health
Birmingham, AL 35294
(205) 934-7032
(205) 975-6341 fax

Vice President
ZACK MANSDORF, PH.D., CIH, CSP
Clayton Environmental Consultants
4575 Hudson Drive
Stow, OH 44224-1773
(216) 686-5100
(216) 686-5105 fax

Past President
HARRY J. ETTINGER, CIH
Los Alamos Nat'l Lab
55 Navajo
Los Alamos, NM 87544
(505) 665-2467
(505) 665-3811 fax

Secretary
JOSEPH L. HOLTSHOUSER, CIH, CSP
The Goodyear Tire & Rubber Co.
1144 East Market Street
Akron, OH 44316-0001
(216) 796-1945
(216) 796-6314 fax

Treasurer
LOREN A. ANDERSON Jr., CIH
PPG Industries
Coatings and Resins Group
4325 Rosanna Dr., P.O. Box 9
Allison Park, PA 15101
(412) 492-5455
(412) 492-5509 fax

Secretary-Elect
JAMES R. THORNTON, CIH, CSP
Newport News Shipbuilding
4101 Washington Avenue, Dept. 027
Newport News, VA 23607
(804) 380-4651
(804) 688-6007 fax

Directors
DAVID A. BISSONNETTE, CIH
PACCAR, Inc.
(206) 455-7480
(206) 453-4900 fax

PATRICIA BROGAN, PH.D., CIH
Ford Motor Company
(313) 594-1610
(313) 390-4237 fax

DEBORAH DIETRICH, CIH
SKC, Inc.
(713) 373-3056
(713) 373-3502 fax

DELBERT FLOWERS, CIH
USDOL/OSHA
(202) 219-8021
(202) 219-4383 fax

JEFFREY S. LEE, PH.D., CIH
University of Utah
(801) 581-7107
(801) 581-7224 fax

STEVEN P. LEVINE, PH.D., CIH
University of Michigan
(313) 995-2531
(313) 763-8095 fax

GAYLA J. MCCLUSKEY, CIH, CSP, ROH
Sun Company, Inc.
(215) 977-6307
(215) 977-6419 fax

DORIS S. REID, CIH
Delta Environmental Cons., Inc.
(704) 541-9890
(704) 543-4035 fax

SANDRA C. WROBLEWSKI, CIH
NATLSCO
(708) 320-2487
(708) 320-4331 fax

Executive Director
O. GORDON BANKS, CAE

April 12, 1995

Docket Office
Docket H-049
U.S. Department of Labor
Occupational Safety & Health Administration
Room N2625
200 Constitution Avenue, NW
Washington, DC 20210

OSHA
DOCKET OFFICER
DATE APR 12 1995
TIME

Dear Sir/Madam:

The American Industrial Hygiene Association (AIHA) expresses its appreciation to the Occupational Safety and Health Administration (OSHA) for the opportunity to provide comments on OSHA's proposed rule on the respiratory protection standard, issued November 14, 1994.

AIHA is the world's largest association of occupational and environmental health professionals. The 11,000 members of AIHA come from government, academia, labor, industry, academia and private business. AIHA is the most diverse professional association dedicated solely to the prevention of workplace fatalities, injury and illness. AIHA's goal is to bring "good science" and the benefit of our workplace experience to the public policy process directed at worker health and safety.

AIHA supports the overall effort to revise the requirements addressing the use of respiratory protection. We believe the comments submitted by AIHA are relevant to the discussion taking place on respiratory protection and urge OSHA to seriously consider these comments when promulgating the final standard.

If there is anything further our organization can do to assist in this worthwhile effort, please contact me.

Sincerely,

Jeremiah Lynch, CIH, CSP, PE
President

Enclosure

American Industrial Hygiene Association
2700 Prosperity Ave., Suite 250, Fairfax, VA 22031-4307
(703) 849-8888 (703) 207-3561 fax

cc: Board of Directors
Respiratory Protection Committee Chair
Occupational Medicine Committee Chair
Respiratory Protection Task Force Chair
O. Gordon Banks, Executive Director

54-208A

AMERICAN INDUSTRIAL HYGIENE ASSOCIATION

COMMENTS TO THE

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

PROPOSED RESPIRATORY PROTECTION RULE

(59 FEDERAL REGISTER 58884 NOVEMBER 15, 1994)

Docket H-049

GENERAL COMMENTS:

In reading the proposal, the American Industrial Hygiene Association (AIHA) found that the Occupational Safety and Health Administration (OSHA) had not integrated the latest information on respiratory protection. AIHA supports using the ANSI Z88.2(1992) standard as the basis for OSHA's proposed rule. In many cases the ANSI Z88.2(1992) standard contains language that is more complete than OSHA's proposal and more accurate. The ANSI Z88.2(1992) standard contains the latest knowledge and experience in what is necessary to run a respirator program. ANSI standards undergo a peer review process that requires the committee to address substantive comments. The ANSI standard is a consensus of opinion and science on what is appropriate for a respiratory protection program.

AIHA supports the overall effort to revise the requirements addressing the use of respiratory protection. Many things have changed since the first issuance of respiratory protection regulations and the piecemeal approach to addressing new information and technology in substance specific standards does not serve anyone's purpose well. In particular, AIHA supports:

- The inclusion of requirements for a written respirator program as well as a qualified administrator to provide overall management of the program
- The periodic training of respirator users because it is critical to their understanding and proper use of the equipment
- The periodic fit testing of all tight-fitting respirators using consistent protocols ensures that the user of respiratory protection can obtain a proper fit, however, AIHA does not agree that the frequency of those fit tests should be driven by exposure to a particular substance

- The need for medical evaluations of all respirator users using the procedures outline in Alternative 3 with some minor changes. AIHA feels that the use of screening questionnaires is a better method of concentrating medical examinations on the respirator users that truly need it rather than establishing a duration of use threshold such as five hours per week

- The continued use of exposure assessments to ensure that respirators are properly selected.

- AIHA also supports including all the OSHA specific standards in all industries as part of the proposed revisions. The November 11, 1994 published proposal did not include any proposed changes to some of the General Industry substance specific standards such as Benzene (1910.1028 issued 9/11/87), Formaldehyde (1910.1048 issued 12/13/88), Methylenedianline (1910.1050 issued 5/27/92), Cadmium (1910.1027 issued 9/14/92), as well as the majority of the Construction (1926) substance specific standards, the Shipyard standard for Asbestos (1915.0001 issued 8/10/94) and the Agriculture standard for Cadmium (1928.1027 issued 4/23/93). AIHA feels that these standards should be part of this rulemaking effort to standardize the regulations applicable to respirator use.

AIHA believes that fit testing specifications are useful, but they should not be written such that they exclude new and existing technology. Explicitly mentioning terminology based on old technology, such as those referring to exposure chambers, particle generators and counters, could exclude procedures such as Portacount and pressure degradation measurements. The regulation should not be written in a way that discourages technical improvements.

On the subject of respirator selection, OSHA should not specify the number of manufacturers/models which should be made available. This should be a performance specification rather than a minimum fixed requirement. Since the intent is to have comfortable good fitting respirators, employer flexibility should be permitted due to varying sizes of respirator user populations. Additionally this requirement covers SCBAs, and as such would dramatically increase the cost of compliance without permitting alternate solutions to address the issue of comfortable, good-fitting respirators. Application of the multiple manufacturer requirement to SCBAs will by itself destroy the validity of the regulatory impact analysis since a single unit costs more than the total cost of all revisions per establishment as estimated by OSHA.

OSHA has chosen to use the assigned protection factors that are listed in the NIOSH respirator decision logic (RDL). OSHA chose the National Institute for Occupational Safety and Health (NIOSH) values rather than the more recent values listed by the ANSI Z88.2(1992) since "... some of the provisions of the ANSI standard appear to contradict specific information which OSHA considers reliable. In particular, the ANSI recommended protection factors disagree substantially with recommendations by NIOSH."

Unfortunately, the NIOSH RDL used fewer studies than were available to the ANSI committee and could not use at all data that has been generated since 1986. This has resulted in assigned protection factors that are different between these groups. The Industrial Safety Equipment Association (ISEA) has submitted to OSHA a listing of twenty-five respirator studies that represent the data base on workplace protection factor (WPF) studies. NIOSH lists in the references to the RDL six WPF studies. With NIOSH there is no information contained in the RDL that specifies which data were used in reaching an assigned protection factor. The NIOSH assigned protection factors were published without any public input. In contrast, the ANSI Z88.2(1992) assigned protection factors were accepted after a peer review process.

Attachment I to these comments is an article that has been accepted for publication in the *American Industrial Hygiene Association Journal* that supports an assigned protection factor of ten for half-mask respirators which includes both disposable and elastomeric types.

The NIOSH and ANSI assigned protection factors differ for powered-air purifying respirators and supplied-air respirators because each group used different definitions for some of the devices. NIOSH uses only two categories of repiratory inlet covering for these repirators: loose-fitting and tight-fitting. ANSI uses four categories: loose-fitting facefiece, hood/helmet, half-mask, and full-facepiece.

Looking at the studies cited by NIOSH in the RDL, there are no studies listed for what ANSI calls a helmet/hood. All the studies listed are with the ANSI defined loose-fitting facepiece. If we define the NIOSH loose fitting class as a loose-fitting facepiece, then ANSI and NIOSH agree on the assigned protection factor for both PAPRs and continuous flow respirators that use this respiratory inlet covering.

With one exception, the tight-fitting powered-air purifying respirator studies cited by NIOSH tested units with half-mask facefieces. The only study that tested a full-facepiece PAPR was conducted in a silica bagging operation (Myers, W. R. and M. J. Peach: Performance Measurements on a Powered Air-Purifying Respirator Made During Actual Field Use in a Silica Bagging Operation. Ann. Occup. Hyg. 27(3):251-259 (1983)). The authors reported that leakage of silica occurred where the breathing tube connects to the blower, which could have let unfiltered air bypass the filter and enter the blower housing. Thus this study may not predict actual performance of the PAPR. If the study by Myers and Peach is not used, the remaining studies for half-mask PAPRs support an assigned protection factor of 50 as listed by ANSI. There is one full-face PAPR study (Colton, C. E., H. E. Mullins and C. R. Rhoe: "Workplace Protection Factors for a Powered Air-Purifying Respirator". [Paper presented at the 1990 American Industrial Hygiene Conference, Orlando, Florida (May, 1990)), that was conducted in a secondary lead smelter.] The authors found that the geometric mean WPF was 10300 and the best estimate of the fifth percentile WPF was 1400. This is consistent with the APF of 1000 assigned to full-facepiece PAPRs by ANSI.

In summary, OSHA has chosen the assigned protection factors listed by NIOSH that are not well documented. In several cases, the NIOSH assigned protection factors contradict what

one would expect based on construction differences between types of respirators. Half-mask and full- facepiece continuous flow and powered air purifying respirators show no difference in performance rating according to NIOSH while they do in negative and pressure-demand modes. AIHA believes the ANSI Z88.2(1992) standard assigned protection factors are the appropriate values for OSHA to use in the respiratory protection standard.

SPECIFIC COMMENTS:

(a) Scope and Application

The position of AIHA is that all use of respiratory protection should be covered by an employer's respiratory protection program. That includes both voluntary use as well as required use. Both groups should participate in all elements of the respiratory protection program. An individual desiring to wear a respirator to obtain some level of comfort or to further reduce their exposure to a chemical in the workplace should receive the full benefits of an established program; training to convey proper knowledge in equipment selection maintenance and use; medical evaluation to confirm that its use will not present a risk to the individual; and fit testing to confirm that the equipment fits properly and workplace surveillance to confirm that the equipment being utilized is suitable for the exposure level.

OSHA has expressed its intent in the preamble on page 58895 column 3 to interpret the term "necessary" in the above sentence to include employee exposure situations where an OSHA PEL is exceeded or they warrant a 5(a)(1) citation under the OSH Act. The proposed standard provides a definition for the term "hazardous exposure level" which would use available occupational exposure limits to select appropriate respirators where no PEL exists and the employer chooses to use respirators. This also includes a requirement for the employer to set exposure limits if none exist. While AIHA supports the use of exposure limits other than OSHA PEL's AIHA does not believe it is necessary for the employer to set exposure limits in each case. AIHA supports the language that is used in the ANSI Z88.2 standard that the employer:

> *"Determine whether there is a published Threshold Limit Value, Permissible Exposure Limit, or any other available exposure limit or estimate of toxicity for the contaminant(s)."*
>
> ANSI recognizes that for most chemicals a definitive exposure limit will not exist The process of setting an exposure limit for these materials though is not a simple action. ANSI recognizes this and requires that an estimate of toxicity be made, allowing professional judgment to be used.

(b) Definitions

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). The simplest approach to correct this problem would be to adopt the Z88.2-1992 definitions.

It is recommended that the definition for "adequate warning properties" be revised so that the word "chemical" is replaced by "gas or vapor" to make it clear that warning properties are not a concern with particulates.

It is recommended that the definition of "assigned protection factor" be revised to read as follows: "Means 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."

It is recommended that the definition of "atmosphere-supplying respirator" change its use of the word "air-supplied" to "supplied air" to be consistent with 30 CFR 11 and OSHA's own SAR definition included in this proposed revision.

It is recommended that the definition of disposable respirator be expanded to address maintenance and repair issues. A suggested revised definition would read "disposable respirator means a respiratory protective device which cannot be resupplied 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" limits existing accepted and potential future technology. AIHA recommends the following definition be used: "Fit factor means a quantitative measure of the fit of a particular respirator to a particular individual."

It is recommended that in the definition of "hazardous exposure level" reference to the TLVs should specify the edition. If it is intended to apply to future editions, it would be considered delegation of authority from OSHA to ACGIH and be a violation of the Administrative Procedures Act.

The definition for "immediately dangerous to life or health or IDLH" taken literally includes chronic toxins such as asbestos since a delayed adverse health effect is possible from a high exposure. AIHA recommends that they be excluded so that only the substances with a delayed effect expected to occur in the immediate future like oxides of nitrogen would be included.

It is recommended that the definition for "maximum use concentration (MUC) be revised to use the OSHA proposed term of "hazardous exposure level" in place of "permissible exposure limit".

It is recommended that the name of the definition "oxygen deficient atmosphere" be changed to "Oxygen deficient atmosphere-not IDLH" for clarity.

The definition of "positive pressure respirator" excludes PAPRs as well as hoods, helmets and loose-fitting facepieces. The following definition is more accurate since it includes all respiratory inlet coverings and acknowledges that positive pressure is not necessarily maintained all the time: "Means a respirator in which the pressure inside the respiratory inlet covering is normally positive with respect to ambient air pressure. This includes powered air-purifying, pressure demand and continuous flow respirators."
The definition for "pressure demand" is inaccurate since the positive pressure varies during the respiration cycle and with work rate. In addition, AIHA feels that the term "substantially maintained" is vague. AIHA recommends a revised definition of "pressure demand" means: 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 "quantitative fit test (QNFT)" definition is limited since it is based on existing technology. AIHA recommends a revision to read as follows: "A fit test that uses an instrument to measure the challenge agent inside and outside the respirator."

The definition of "respirator" is made vague by its use of the term "intended." The wearer, the employer, or the designer of the device all could be considered the source of the decision on what type of protection was intended. Employees sometimes wear bandanas to "protect" against dust exposures. Safety and health professional do not consider these to be respirators. It is recommended that the word "designed" be substituted for the word "intended."

The definition of "service life of a chemical or organic vapor cartridge or canister" is unclear since breakthrough percentage, humidity and other test conditions, are not specified. It would also appear to require manufacturers to run breakthrough studies for every possible contaminant. They should be held responsible to determine breakthrough for substances used in the NIOSH certification tests. Also, it would not recognize any other source of cartridge/canister test data other than the manufacturer.

Additionally, the term "break though" requires a definition. Is it the first trace or the PEL or what? Analytical sensitivity could determine actual breakthrough which would vary among different species.

A recommended revision is as follows: "Service life means the period of time that a respirator provides adequate protection to the wearer."

(c) Respiratory protection program

It is recommended the paragraph (c)(1)(ii) be revised as follows "Medical evaluations of employees who are authorized by the employer to wear respirators;" This would clarify that medical reviews are to cover both voluntary and required use. Except for presence of the contaminant, there is no difference to employee health.

(d) Selection of respirators

Employers should not be forced to provide employees with respirators when they are not considered to be necessary. This should be a decision of the employer. It is therefore recommended that paragraph (d)(1) be revised as follows: "The employer shall provide respirators and respiratory equipment at no cost to employees when such equipment is required by the employer to protect the health of the employee."

Since the word "elastomeric" is not defined in (d)(2), it could be interpreted to apply to SCBAs and other air-supplied respirators. This would dramatically increase the cost of compliance. OSHA's estimate of the regulatory impact for the Chemical and Allied Products quotes a cost of $627 per establishment. The purchase of just one SCBA would greatly exceed that dollar value and therefore render this cost estimate invalid.

This multiple size and manufacturer requirement does not permit employers to manage use of respirators. Since the respirator wearer already has to pass a fit test before they can use the respirator, proper sizing and comfort is already controlled.

Additionally, it is not necessary to require employers to have respirator models from two manufacturers since several manufacturers now have two completely different models of half-mask respirator with different fit characteristics. If an employer makes both models available, the intent of this paragraph is satisfied. The wording of the paragraph should be modified to address this issue.

It would be better to use language that allows for the variation that occurs in different workplaces. AIHA strongly suggests the following wording taken from ANSI Z88.2-1992 (9.3.1):

"(d)(2) No one size or model of respirator will fit all types of faces. Different sizes and models will accommodate more facial types. Therefore, 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 requirement vary for workplaces. For example, in a workplace with four workers, one model and size may fulfill the requirement; whereas a workplace with one hundred wearers may require different models in various sizes."

The requirement outlined in (d)(3) seems to place an unreasonable burden on each employer by requiring an evaluation of each work situation. It is suggested that the work situation be defined to permit employers to use estimates of exposure in addition to data that is representative of a task.

AIHA recommends that paragraph (d)(3)(vi) be expanded to include the potential for upset conditions, such as chemical spills, leaks or fire, which may require emergency use respirators. The suggested wording would be "(d)(3)(vi) the nature of the work operation or process and the potential for the emergencies to occur".

The requirement in (d)(3)(ix) to review fit-test results is not needed. Befor someone can be assigned to wear a respirator, they are required to pass a fit test. Once someone has passed the fit-test with a respirator, then they can use that repirator up to the limits set by the assigned protection factor. Respirators can only be selected for situations that are within the assigned protection factor, therefore there is no need to review fit-test results each time a selection is made.

It is suggested that paragraph (d)(3)(xi) be deleted. It sounds like NIOSH's responsibility as part of the approval process.

AIHA supports the use of the ANSI Z88.2-1992 standard's assigned protection factors (APF) rather than the NIOSH values cited by OSHA in (d)(5) as stated in our opening remarks. OSHA does not explain why it believes the NIOSH protection factors are valid. NIOSH states in the Respirator Decision Logic that most of their protection factors are based on quantitative fit tests done almost 20 years ago. It is well documented that QNFT results do not correlate with workplace performance. Secondly, OSHA does not address the fact that the NIOSH protection factors are higher than the ANSI protection factors for several types of device. For example the NIOSH APF is 20 times higher for pressure demand half masks than the ANSI value; it is twice as high for pressure demand full facepieces. Additionally, the development of the ANSI APFs were open to debate while the NIOSH values were not.

To improve clarity the first sentence of (d)(5) should be revised to include the word "appropriate" as follows "(d)(5) The employer shall make appropriate types of respirators available for selection ...".

AIHA recommends that (d)(8) and (d)(9) be revised and combined as follows:
(d)(8) Air-purifying respirators shall not be used for a hazardous gas or vapor with poor or inadequate warning properties unless at least one of the following conditions is met:

(i) Their use is permitted under the provisions of a substance specific OSHA standard,

(ii) The respirator has an end of service life indicator approved by NIOSH for use with the specific chemical, or

(iii) A change schedule has been implemented to assure that air-purifying cartridges and/or canisters are replaced before their useful service life has expired, based upon documented service life data, airborne concentration of the gas or vapor, relative humidity, presence of other gases and vapors, temperature, work rate, and duration of exposure, and the gas or vapor does not have a ceiling limit that is exceeded by the warning properties."

The purpose of the suggested change of the word "chemical" in (d)(8) to "gas or vapor" is to avoid including particulates in the definition which is not appropriate.

The purpose of the proposed change from the specification of "... before 80 percent of their useful service life has expired ..." to "... before their useful service life has expired ..." is to make it consistent with ANSI Z88.2-1992.

The general combination of both (d)(8) and (d)(9) with the elimination of the permitted use of cartridges where the warning properties were up to three times the "hazardous exposure level" (d)(8)(ii) is to address the current NIOSH-approved use of mercury cartridges with end of service life indicators. Mercury does not have a recognized warning property level and therefore the use of the approved mercury cartridge would be eliminated by the originally proposed wording. Use of a limit of three times the hazardous exposure level would also limit future advances in end of service life indicator technology

Other suggested changes address: the lack of need to worry about predicting service life for filters because breathing resistance is the indicator of the need to change them; and the need to consider other factors impacting cartridge service life including relative humidity, work rate, temperature, and the presence of other gases or vapors.

Additionally, AIHA is not in agreement with OSHA's justification for the policy to limit the use of air-purifying respirators in the absence of adequate warning properties to three times the hazardous exposure level given on page 58904 of the federal register (11/15/94) (top of third column). Assigned Protection Factors have nothing to do with detection of warning properties (or vice versa). OSHA also refers to a protection factor table in a proposed 42 CFR Part 84 which has never been published.

AIHA recommends that the values used in Table I Column 2 for 5001 to 6000 feet of 19.5 percent be replaced with 20.0 percent, 6001 to 7000 feet of 19.5 percent be replaced with 20.8 percent, 7001 to 8000 feet of 19.5 percent be replaced with 20.9 percent and at above 8000 to 14,000 feet of 19.5 percent (as identified in (d)(10)(i)) be replaced with 20.9 percent oxygen. This would utilize some of the more conservative thinking ANSI Z88.2-1992 where they recommended that at reduced oxygen partial pressures less than 122 mm Hg use of an atmosphere supplying respirator is appropriate. It also recognizes OSHA's position that at higher elevations, oxygen enrichment is not needed. AIHA also does not agree with permitting the use of air-purifying respirators

at elevations above 8000 feet where the percent oxygen level is below 20.9 percent. This level is considered by ANSI Z88.2-1992 and OSHA (federal register 11/15/94 page 58906 column 1 first paragraph) to be an oxygen deficient IDLH atmosphere.

Additionally, AIHA would rename Column 2 of Table I as "Oxygen Deficient Not IDLH" to avoid confusion with Column 3 of Table I.

A correction to (d)(10)(iii) to properly cite Table I instead of Table III is needed. Therefore, based upon these and earlier comments, AIHA recommends (d)(10) to be renumbered and reworded as follows:

"(9) Where an oxygen deficient atmosphere or an oxygen deficient IDLH atmosphere exists, appropriate respirators shall be selected as follows:

(i) Either an air-purifying respirator or atmosphere supplying respirator may be used where an atmosphere has a measured oxygen content at or above the values in Table I Column 2 (oxygen deficient not IDLH) between 0 and 14,000 feet.

(ii) An atmosphere-supplying respirator shall be used for oxygen deficient not IDLH atmospheres with a measured oxygen content level at or above the values in Table I column 3 (oxygen deficient IDLH) between 0 and 14,000 feet.

(iii) Either a full-facepiece pressure demand SCBA or a combination full facepiece pressure demand supplied air respirator with auxiliary self contained air supply shall be used for oxygen deficient IDLH atmospheres with a measured oxygen content below the values in Table I column 3 between 0 and 14,000 feet.

(iv) Either a pressure demand SCBA or a combination supplied-air with an auxiliary self-contained air supply shall be used when confince space that containes less than the normal 20.9 percent oxygen, unless the source of the oxygen reduction is understood and controlled.

Table I.-Oxygen Percentages Constituting Oxygen Deficient and Oxygen Deficient IDLH Atmospheres

Column 1 altitude above sea level (in feet)	Column 2 percent oxygen below which an oxygen deficient not IDLH atmosphere exists	Column 3 percent oxygen below which an oxygen deficient IDLH atmosphere exists
0 to 3000	19.5	16.0
3001 to 4000	19.5	16.4
4001 to 5000	19.5	17.1
5001 to 6000	20.0	17.8
6001 to 7000	20.8	18.5
7001 to 8000	20.9	19.3
Above 8000 to 14,000	20.9	19.5(1)

(1) For altitudes above 8000 feet, an oxygen deficient IDLH atmosphere exists when the oxygen level falls below 19.5%.

(e) Medical evaluation

OSHA should adopt the regulatory language identified as Alternative 3 on page 58911 in the preamble with two exceptions: (1) change the wording of (e)(1)(iii) to include any employee wearing an SCBA as follows: "(e)(1)(iii) A medical examination shall be administered to any employee who is assigned to wear an SCBA" and (2) delete the requirement found in (e)(1)(vi)(B) to supply the examining professional with a list of the substances the employee will be exposed to. OSHA already has an ANPRM on medical surveillance. This information should be the subject of that rulemaking effort and does not add anything needed to the information necessary to determine an individual's ability to wear a respirator.

AIHA believes that Alternative 3 with the suggested changes reflects the current state of knowledge regarding the stresses of wearing respirators and provides for adequate follow up for employees who are most likely to have problems. In the preamble OSHA refers to three sample questionnaires in Appendix C intended to support this alternative that were not included in the Federal Register on 11/15/94.

AIHA considers the five-hour per week threshold in the current proposal to be unacceptable due to the potential risk for emergency responders and firefighters who wear SCBA intermittently as well as the vagueness which will likely cause confusion between those taking it literally and those taking it in the spirit of its intent. It should be noted that neither 1910.120 nor 1910.156 would provide medical evaluations for workers in these situations in the absence of a 1910.134 requirement.

The purpose of identifying all the substances the employee will be exposed to ((e)(1)(ii)) is unclear when providing the physician with the information needed to evaluate the individual's ability to wear a respirator. OSHA already has an ANPRM on medical surveillance. This information would more appropriately fall under that rulemaking effort. Additionally, it would seem that if it were deemed necessary then it should be limited to those chemicals for which a respirator will be worn.

(f) Fit testing

AIHA recommends that the (f)(1) be reworded as follows: "(f) Fit testing--(1) The employer shall ensure that when employees are required to wear tight-fitting respirators they pass a fit test as outlined in (f)(2) through (f)(9)." This wording reduces the ambiguity of the proposed language recognizing that only tight-fitting respirators need to be fit tested. It also eliminates the potential permitted use of respirators at fit test values rather than at their assigned protection factor based upon passing a fit test.

AIHA recommends that the (f)(2) be rewritten to the following: "(f)(2) The employer shall ensure that an employee is fit tested prior to initial use of the respirator facepiece, whenever a different fitting respirator facepiece (for example: make or size) is used, and annually thereafter." This suggested change addresses some respirator manufacturers' who offer multiple models of half-face respirators some of which may or may not come from the same mold. Additionally, this permits employers to utilize the same fit test for a manufacturer who offers the same facepiece mold for both an air-purifying and atmosphere-supplying respirator but the model number of the respirator is different.

AIHA recommends clarifying the relationship and extent of fit testing outlined in (f)(6)(i)(A) by indicating that the employee passes a fit test and that passed test only applies to the employee not all employees. It therefore should be reworded as follows: "(f)(6)(i)(A) Qualitative fit testing shall be performed in accordance with the established protocols specified in section II of Appendix A or new protocols that meet the minimum criteria contained in section I of Appendix A. If the employee passes the qualitative test the employee may wear the respirator in atmospheres no greater than ten times the hazardous exposure level."

Since some currently accepted technology do not employ chambers and this may restrict any future development, AIHA recommends the deletion of the reference to a test chamber in (f)(6)(i)(B). It should read as follows: "(f)(6)(i)(B) Quantitative fit testing shall be performed in accordance with an established protocol specified in section II of Appendix A or a protocol that meets the minimum criteria contained in section I of Appendix A. The test subject shall not be permitted to wear a half mask or quarter facepiece respirator unless a minimum fit factor ten times the assigned protection factor is obtained. The respirator may not be worn in concentrations greater than ten (10) times the hazardous exposure level regardless of the measured fit factor."

AIHA recommends clarifying the relationship and extent of fit testing outlined in (f)(6)(ii)(A) by indicating that the employee passes a fit test and that passed test only applies to the employee not all employees. It therefore should be reworded as follows: "(f)(6)(ii)(A) Qualitative fit testing shall be performed in accordance with the established protocols specified in section II of Appendix A or new protocols that meet the minimum criteria contained in section I of Appendix A. If the employee passes the qualitative fit test then the employee may wear that respirator in atmospheres no greater than ten (10) times the hazardous exposure level."

Since some currently accepted technology does not employ chambers and this may restrict any future development, AIHA recommends the deletion of the reference to a test chamber in (f)(6)(ii)(B). It should read as follows: "(f)(6)(ii)(B) Quantitative fit testing shall be performed in accordance with the established protocol specified in section II of Appendix A or a new protocol that meets the minimum criteria contained in section I of Appendix A. The test subject shall not be permitted to wear a full-facepiece respirator unless a minimum fit factor ten times the assigned protection factor is obtained. The

full-facepiece respirator may not be worn in concentrations greater than fifty (50) times the hazardous exposure level regardless of the measured fit factor."

AIHA recommends that (f)(6)(iii)(B) be revised so that an attachment for the purpose of conducting the fit test may be used as well as permit the fit testing of either a tight-fitting atmosphere-supplying or tight-fitting powered air-purifying respirator in the negative pressure mode. "(f)(6)(iii)(B) During the fit test either the respirator is only used in the negative pressure mode of operation or if the manufacturer makes available an identical facepiece as part of an air-purifying respirator model, then the facepiece is tested in that fashion with only the addition of attachments for the purpose of conducting the fit test."

AIHA recommends that since (d)(6) is proposed to be reserved that reference to it be dropped in (f)(6)(iii)(B)(1) and (2).

(g) Use of respirators

AIHA recommends that (g)(2) be revised as follows: "(g)(2) The employer shall develop and implement specific procedures for the use of respirators when they are to be used in atmospheres where oxygen deficiency or the concentrations of a hazardous chemical are unknown and/or potentially immediately dangerous to the life or health (IDLH) of the employees. These procedures shall include the following provisions:" As proposed, the paragraph would require the development of these procedures for all employers using respirators even if the employer only uses dust/mist respirators.

AIHA recommends that (g)(2)(iv) be changed to recognize the NIOSH permitted use of combination full-facepiece, pressure demand, supplied-air respirator with auxiliary self-contained air supply. There may be some limited access workplace conditions which dictate use of SAR/SCBA. The wording should be revised as follows: "(g)(2)(iv) The emergency assistance personnel present shall be equipped with either a full-facepiece, pressure demand, self-contained breathing apparatus or combination full-facepiece pressure demand, supplied-air respirator with auxiliary self-contained breathing apparatus.

In (g)(3), since pressure demand is one type of positive pressure respirator either eliminate the words "pressure demand" or change "positive pressure" to "continuous flow". Additionally, this paragraph needs to address loose-fitting facepieces, as is the case in Z88.2-1992 (7.5.1). The suggested revised wording is as follows: " (g)(3) The employer shall not permit negative or positive pressure respirators which depend for effective performance on a tight- or loose-fitting facepiece-to-face seal to be worn by employees with conditions that prevent such fits. Examples of these conditions include facial hair that interferes with the facepiece seal, absence of normally worn dentures, facial scars or headgear that projects under the facepiece seal."

In (g)(6), because filters are for particles (see definition) and warning properties are associated with gases and vapors the following revised wording is recommended: "(g)(6) The employer shall permit employees to leave the respirator use area promptly to change the cartridge(s) or canister or replace air-purifying respirators whenever they detect the warning properties of the gas or vapor."

AIHA recommends that since filters are for particles by definition, and therefore they will never remove chemical vapor that the phrase "or chemical vapor breakthrough be removed from (g)(7). It should be revised as follows "(g)(7) The employer shall permit employees to leave the respirator use area promptly to change the filter elements of air-purifying respirators whenever they detect a change in breathing resistance."

AIHA recommends in (g)(10) that the term "facepiece seal check" be changed to "fit check" to recognize common terminology as described by ANSI Z88.2-1992.

The performance-oriented language of the existing standard is more reasonable. Cleaning and disinfecting of individually assigned respirators should be done "as needed" to assure proper respirator performance and to preclude skin irritation or toxicity hazards from accumulation of materials. Disinfecting an individually issued respirator is probably not necessary at all unless the "contaminant" is biological in nature. AIHA recommends the following wording be used: "(h)(1)(i) Routinely used respirators issued for the exclusive use of an employee shall be regularly cleaned and disinfected;"

AIHA recommends that the start of (h)(2)(ii) be revised as follows: "(h)(2)(ii) Where emergency use respirators are available, they shall be accessible . . .". The current wording implies that emergency respirators are always required.

AIHA recommends (h)(2)(iv) be revised as follows: "(h)(2)(iv) Respirators shall be packed or stored to prevent deformation of the facepiece or other component parts." Neither the exhalation valve nor any other part of a respirator should be stored in a distorted position.

Paragraph (h)(3)(i)(A) and (B) include SCBAs. This same language is in the existing 1910.134, and many people believe that the monthly inspection is all that is required for an SCBA. To clarify the regulatory language, AIHA recommends moving (h)(3)(i)(C) into (h)(3)(ii) and making it two subparagraphs as follows:

"(h)(3) Inspection.

(i) The employer shall ensure that respirators are inspected as follows:

(A) All respirators used in non-emergency circumstances shall be inspected before each use and during cleaning after each use; and

(B) All respirators maintained for emergency situations shall be inspected at least monthly, and checked for proper function before and after each use. Emergency escape respirators shall be inspected before being carried into the workplace;

(ii) The employer shall ensure that the respirator inspections include the following:
(A) A check of respirator function, tightness of connections and the condition of the facepiece, headstraps, valves, connecting tube, and cartridges, canisters or filters; and,
(B) A check of rubber or elastomer parts for pliability and signs of deterioration.
(C) Assurance that the cylinder pressure of self-contained breathing apparatus is at least 90 percent of the manufacturer's recommended pressure. Cylinders below 90 percent shall be recharged."
(D) A functional check of the regulator and warning device of self-contained breathing apparatus.

AIHA recommends retaining the existing requirement to record dates and findings as well as add a requirement to record remedial actions. AIHA believes the retention period should be one year; this allows tracking of repair history and as well as recurring problems which may indicate design defects. AIHA therefore recommends that the following sentence be added to the end of (h)(3)(iii) "A record shall also be maintained for one year, possibly in a central location, of the inspection dates, findings and any remedial actions taken."

AIHA recommends changing the term "atmosphere-supplying" to "supplied air" in (i)(2) to recognize the permitted use of compressed oxygen in appropriately approved NIOSH respirators. AIHA also recommends the addition of (from Z88.2- 1992): "Oxygen concentrations greater than 23.5 percent shall be used only in equipment designed for oxygen service or distribution" to (i)(2).

With the above changes, AIHA recommends that (i)(3) be deleted due to redundancy.

AIHA recommends that (i)(4)(i) recognize that DOT requirements found in 49 CFR Part 173 also apply breathing air cylinders.

AIHA recommends that the moisture specifications of ANSI/CGA G7.1-1989 Grade D air be used in (i)(4)(ii). The ANSI/CGA standard specifies a dew point 10° F below ambient at 1 atmosphere. OSHA has not provided any reason for the change to Celsius or to line pressure.

AIHA recommends that (i)(4)(iii) be changed to be consistent with ANSI/CGA G7.1-1989 which is roughly equal as well as consistent in the use of dew point terminology. ANSI/CGA G7.1 recommends a dew point of -50°F. It would be revised as follows: "(i)(4)(iii) The moisture content in compressed air cylinders shall not exceed a dew point of -50°F at 1 atmosphere."

The references used in (i)(6) are out of date. AIHA recommends the following current versions be substituted in (i)(6): Z48.1-1954 (R 1971) is now ANSI/CGA C-4-1990 and BB-A-1034a is now BB-A-1034-B-1985.

(j) Identification of filters, cartridges, and canisters --

AIHA recommends that (j)(1) be deleted since labeling issues are addressed in (j)(2) and mislabelling and color coding issues are outside the control of the employer.

AIHA recommends that (j)(2) be revised to address the following issues: (1) As written, an employer is in violation if, for example, a label is covered with paint overspray during use; and (2) Some OSHA substance-specific standards require that cartridges be dated by the employee to indicate when they first were used. Some employers may use this method to control cartridge usage even when a substance-specific standard does not apply. This type of alteration should be permitted. It is therefore recommended that the following wording be used: "(j)(2) The employer shall ensure that the existing NIOSH approval label on a filter, cartridge, or canister is not intentionally removed, obscured or defaced while they are in service in the workplace except if it is to record initial use information."

(k) Training

AIHA recommends that the training on respiratory hazards be limited to those substances for which a respirator is required to be worn. Expansion beyond that which applies to the use of respiratory protection would fall under a revision to the Hazard Communication Standard. Therefore a suggested revision is "(k)(1)(i) Nature, extent, and effects of respiratory hazards for which the employee is required to wear a respirator as required under the Hazard Communication standard (29 CFR 1910.1200);"

(l) Respiratory protection program evaluation

(m) Recordkeeping and access to records

(n) Effective date

(o) Appendixes

Appendix A: Fit Testing Procedures (Mandatory)

I. New Fit Test Protocols

AIHA recommends that the statement concerning the concentration of test agent permitted to be generated during a test be clarified in Appendix A Section I.A.2.(a). Since an occupational exposure is related to an individual over a set time period the requirement should be modified as follows: "Appendix A Section I.A.2.(a) The test agent shall be relatively nontoxic. The test subject's exposure as a result of testing, regardless of the respiratory protection worn, shall not exceed an OSHA permissible exposure limit, the ACGIH threshold limit value, or any known recommended exposure limit when there is no OSHA PEL or ACGIH TLV, and not create a health or physical hazard for the test subject or operator." For example: Consider a test agent with a TWA limit of 100 ppm used for fit testing at a concentration of 200 ppm. The "concentration generated" has exceeded the exposure limit; the "test subject's exposure" has not, because the test takes only eight minutes.

The current wording used in Appendix A Section I.A.2.(h) in reference to "contamination of the area ..." is vague because the amount of test agent required to be present to influence the outcome of testing will vary based upon test agent and individual. AIHA suggests a revision as follows: "Appendix A Section I.A.2.(h) Precautions shall be taken to avoid allowing the test agent from the fit test area to contaminate the area where the test subjects are tested to determine their response to the threshold screening concentrations in sufficient amounts to influence their response. Significant contamination of the area where the threshold screening test is administered by the test agent from the fit test area may render any tests unacceptable."

B. Validation Criteria for Qualitative Fit Tests

Appendix A Section I.B.2.(b) appears to require comparison of the new method with an old aerosol QNFT system. The aerosol system has been shown to be subject to in-facepiece sample bias, lung retention of inhaled aerosol, and problems with data interpretation. No studies have ever shown that aerosol quantitative fit factors correlate with workplace protection. OSHA should at least indicate that, even though aerosol QNFT has never demonstrated its precision, accuracy, or value, it is used as the reference method because it is all we have at the moment. To do less than this, AIHA feels is misleading.

A comma should be placed between the words "exercises" and "sizes" in Appendix A Section I.B.2.(b) to clarify the intent.

C. Minimum Criteria for a Valid Particle Counting Quantitative Fit Test

AIHA recommends that there not be a separate validation criterion for particle counting QNFT (Appendix A Section I.C); all new methods should be evaluated by the same criteria.

The requirements outlined in Appendix A Section I.C.2 for an aerosol generator, control of test concentration, and aerosol characteristics will prevent currently accepted use of fit test equipment like the Portacount from ever being part of a validated method.

AIHA recommends that the statement concerning the concentration of test agent permitted to be generated during a test be clarified in Appendix A Section I.C.2.(b). Since an occupational exposure is related to an individual over a set time period the requirement should be modified as follows: "Appendix A Section I.C.2.(b) The test subject's exposure to the aerosol/gas as a result of testing shall not exceed an OSHA permissible exposure limit, the ACGIH threshold limit value, or any known recommended exposure limit when there is no OSHA PEL or ACGIH TLV, and not create a health or physical hazard for the test subject or operator." For example, consider a test agent with a TWA limit of 100 ppm used for fit testing at a concentration of 200 ppm. The "concentration generated" has exceeded the exposure limit; the "test subject's exposure" has not, since the test takes only eight minutes.

AIHA recommends that the term "appreciably absorbed or retained" when referring to Appendix A Section I.C.2.(c) be permitted so long as it is known and accounted for in the calculations. The size distribution of the test aerosol should not be specified for this method. Design specifications like this preclude the development of new technology.

The statement "particle size is capable of penetrating deficiencies...." in Appendix A Section I.C.2.(e) is vague and should be deleted.

D. Validation Criteria for Quantitative Fit Test Protocols

AIHA recommends that OSHA define the level of "accuracy" of the protocol found in Appendix A Section II.C as well as describe how it arrived at this definition. This will permit the determination of the acceptability of a new quantitative method as proposed in Appendix A Section I.D.1.

E. Minimum Criteria for New Technology

AIHA recommends the following revisions based upon respirator fit tests measuring fit, not protection: "Appendix A Section I.E.2 equipment measuring; respirator efficiency; test agent penetration; or fit factors must be capable of reliably detecting and measuring

the test agent, or fit factor with a high degree of accuracy. The limitations of detection and test sensitivity must be known."

AIHA recommends that the statement concerning the concentration of test agent permitted to be generated during a test be clarified in Appendix A Section I.E.6.(a). Since an occupational exposure is related to an individual over a set time period the requirement should be modified as follows: "Appendix A Section I.E.6.(a) The test subject's exposure as a result of testing must be maintained below an established PEL, ACGIH TLV, or recommended exposure level and not create a health hazard or physical hazard for the test subject or associated personnel." For example; Consider a test agent with a TWA limit of 100 ppm used for fit testing at a concentration of 200 ppm. The "concentration" has exceeded the exposure limit; the "test subject's exposure" has not, since the test takes only eight minutes.

About 30 percent of the particles generated in the corn oil systems are retained in the respiratory tract. (Crutchfield, C. D., R. W. Murphy and M. D. Van Ert: A Comparison of Controlled Negative Pressure and Aerosol Quantitative Respirator Fit Test Systems By Using Human Subjects. Am. Ind. Hyg. Assoc. J. 54(1):10-14 (1993)). Will this be used as the criterion used in Appendix A Section I.E.6.(b) for a particle not being considered retained by the airways of the respiratory tract?

AIHA suggests that Appendix A Section I.E.6.(c) provided the unit of measure for the removal percentage of 99.97 percent.

The use of the words "concentration" and "breathing cycle" in Appendix A Section I.E.6.(d) eliminates systems such as the controlled negative pressure method that use air as a test agent. AIHA recommends a revision as follows: "Detection system for test agents must be capable of quantifying the penetration of test agent inside the respirator during the entire test exercise."

F. Validation for New Technological Methods of Determining Respirator Fit

II. Current Fit Test Protocols

AIHA recommends that the first sentence of Appendix A Section II.A.8 be changed to merely require performance of an appropriate fit check. The reference in the part should be to the current ANSI standard (Z88.2-1992). The last word of the last sentence ("tests") should be deleted.

AIHA recommends that Appendix A Section II.A.9 should delete the word "long" next to sideburns. Any sideburn that interferes is undesirable.

AIHA recommends that Appendix A Section II.A.14 be revised to address use of safety equipment as follows: " 14. Test Exercises. The test subject shall perform exercises, in a test environment, while wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with fit, in the manner described."

AIHA recommends that a copy of the Rainbow Passage be included in the regulatory text if it is mentioned in Appendix A Section II.A.14(e).

AIHA recommends that the grimace be removed from the fit testing exercises (Appendix A Section II.A.14(f). This should NOT be included in QLFT protocols, since its purpose is to break the respirator seal (acknowledged by OSHA on federal register page 58919). If this happens, the QLFT will be failed.

B. Qualitative Fit Test (QLFT) Protocols.

There is no need to dry off the labels applied to the odor and blank test jars in the isoamyl acetate protocol as described in the Appendix A Section II.B.2.(a)(7), which is what this sentence requires. Delete these words.

AIHA recommends in Appendix A Section II.B.2.(b)(2) that the second sentence be deleted. A person competent to implement an adequate QLFT program will be able to establish an adequate cartridge change schedule. If cartridges are not changed often enough, the result will be excessive test failures, i.e., erring on the side of safety.

In Appendix A Section II.B.2.(b)(7), if IAA is detected during the fit test the test has not failed the individual has failed the fit test. Wording should be changed to say this.

In Appendix A section II.B.2.(b)(8), revise the first sentence as follows: If the subject as failed the fit test, the subject ..." to reflect what truly has failed.

Appendix A Section II.B.2.(b)(9) should be revised as follows: "When the subject wearing the respirator passes the test, its efficiency ..." .

In Appendix A Section II.B.2.(b)(10), the last sentence should be modified as follows: "Whe leaving the test chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self-sealing bag to prevent the test area from being contaminated."

3. Saccharin Solution Aerosol Protocol

AIHA recommends changing the statement in Appendix A Section II.B.3(a)(3) concerning how much the mouth needs to be open from "wide" to "slightly". The mouth

only needs to be slightly open to allow the subject to detect the taste.

AIHA recommends adding "or equivalent" after "nebulizer" in Appendix A Section II.B.3(a)(4).

AIHA recommends that Appendix A Section II.B.3(a)(5) be corrected to read "... check solution consists of 0.83 grams of sodium saccharin USP in 100 cc of warm water. ..."

(b) Saccharin solution aerosol fit-test procedure.

AIHA recommends that smoking be added to the list of "don't do" before the saccharin solution aerosol test in Appendix A Section II.B.3.(b)(1).

AIHA recommends adding "or equivalent" after the word "nebulizer"in the first sentence in Appendix A Section II.B.3.(b)(4).

AIHA recommends changing "wide" to "slightly" in Appendix A Section II.B.7.(b)(6). Wide-open mouth could adversely affect fit and represents a situation not likely to occur in the workplace.

AIHA recommends adding the sentence "A minimum of ten squeezes is required." to Appendix A Section II.B.3.(b)(7).

AIHA recommends correcting the reference from Section VII.A.14 to Section II.A.14 in Appendix A Section II.B.3.(b)(8).

AIHA considers "smell" and "odor" to be inappropriate terms to use in Appendix A Section II.B.4.(b) to describe an involuntary cough. AIHA would revise the wording as follows: "The test subject shall be allowed to inhale a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties."

AIHA recommends identifying what the expected "response" is in Appendix A Section II.B.4(g) by revising it as follows: "... the smoke test without evidence of a response (involuntary cough) shall be given...".

The definitions and description of the fit-test apparatus found in Appendix A Section II C Quantitative Fit Test (QNFT) Protocol are largely based on outdated technology and should be rewritten to reflect the way that QNFT is really done in today's world. Like it or not, most people (including OSHA) use the Portacount.

AIHA recommends that the statement in Appendix A Section II.C.3(e) be clarified about not exceeding an exposure limit. Does this mean TWA exposure? It should be revised as follows: "The combination of substitute air-purifying elements, challenge agent and challenge agent concentration shall be such that the test subject is not exposed in excess

of an established exposure limit for the challenge agent at any time during the testing process based upon the length of the exposure and the exposure limit duration."

AIHA recommends that because of documented problems with aerosol streamlining and other in-facepiece sample biases, probe location and depth should be addressed in Appendix A Section II.C.3(f).

AIHA recommends that the abbreviated QLFT should be optional with the QNFT protocol listed in Appendix A Section II.C.4(b). The initial intent of this pre-test was to save time by eliminating poorly fitting respirators before conducting a QNFT the old way and experience has shown that with the new technology (Portacount); they do not save time. Additionally, using the Portacount in the count mode can give a quicker estimate of fit than fumbling around with smoke tubes, IAA, etc. In either case they should be optional and it should state that clearly.

The last sentence in Appendix A Section II.C.4.(g) contradicts Appendix A Section C.4(h) and OSHA's explanation on page 58920 in the preamble. While AIHA does not support the requirement of three QNFTs to determine acceptability of the fit of a respirator as discussed earlier, it is important to at least remain consistent in the regulation.

Analyzing the same fit test using each of the three methods as described in Appendix A Section II.C.4.(i)(3) will result in a different fit factor. For fit factors near the acceptance level, these differences could become significant. If a procedure for this outdated fit testing method is to be specified, data analysis should be standardized.

AIHA does not agree with the implied position in Appendix A Section II.C.4.(j) since a high fit factor doesn't correlate with workplace protection and, therefore, does not allow the user to claim a protection factor above the assigned protection factor for a half-mask or a full-facepiece, interpreting the result of a quantitative fit test should be treated the same as a qualitative fit test: as a pass/fail result. With this limitation on interpretation of QNFT results, one successful test per subject would be sufficient.

AIHA feels that the individual running the fit test program should be allowed to determine when air purifying elements need to be changed (Appendix A Section II.C.4(l)). The canister/cartridge service life will vary depending on use conditions, and changing at the specified frequencies, based on our experience, would be a waste of money.

Appendix B: Recommended Practices (Nonmandatory)

AIHA recommends in Appendix B changing the phrase "facepiece seal checks" to "facepiece fit checks" to standardize with ANSI Z88.2-1992. AIHA would also

recommend that statements be added to the effect that: "Fit checks are not substitutes for qualitative or quantitative fit tests.

The methods described are intended for elastomeric respirator facepieces. Fit check methods for non-elastomeric facepieces may be performed by following the manufacturer's instructions. A statement to that effect should be added to Appendix B.

AIHA recommends in Appendix B Section II.C that a maximum temperature for the rinse water of 43° C (110°F) be specified as in ANSI Z88.2-1992 rather than 50°C (122°F). Alternately, it would be acceptable to say "follow the manufacturer's instructions for water temperatures".

Since manufacturers cannot anticipate every disinfectant that might be used, it would be better to say ". . .if their use is approved by the manufacturer" in Appendix B Section II.D.3.

AIHA feels that OSHA should explain how to "Test the respirator to ensure that all components work properly "without contaminating the respirator. If they cannot, it should be deleted from Appendix B Section II.H.

Appendix C: Medical Evaluation Procedures (Nonmandatory)

AIHA also supports OSHA's consideration of incorporating the Medical Evaluation Criteria found in the NIOSH Respirator Decision Logic (87-108), pages 30-34 and the Background Information on pages 52-55, with minor modification. NIOSH offers the most practical description of a functional medical evaluation program that has been published. The NIOSH advice should be supplemented with sample questionnaire such as that found in ANSI Z88.6-1984.

XV. Proposed Substance Specific Standards Revisions

AIHA recommends that OSHA standardize the frequency of fit testing of all respiratory protection. There is not any data supporting the need to conduct respirator fit testing at frequencies of every six months for substances such as asbestos (1910.1001, 1926.58/1926.1101), lead (1910.1025, 1926.62) and acrylonitrile (1910.1045). AIHA feels that this requirement wastes time and resources without providing any benefit.

AIHA believes that there is not any justification for limiting qualitative fit testing for use in fit testing only half mask respirators (Asbestos, Benzene, etc.). Nor does the need to perform quantitative fit testing have anything to do with whether you have more than a specific number of employees wearing respirators (acrylonitrile-10; inorganic arsenic-20).

AIHA recommends that the respiratory protection selection tables for Acrylonitrile, Cotton Dust, and Ethylene Oxide be revised to reflect the availability of IDLH values. Since NIOSH has recently revised many and added some new IDLH values and is currently reviewing comments received on standard criteria for revising and developing them, AIHA recommends OSHA recognize this issue. While AIHA is not endorsing the NIOSH IDLH values because these exposure values have not been open to public comment their presence needs to be addressed to avoid confusion.

AIHA recommends that OSHA consider inclusion by reference of 1910.134 (e) requirements for medical evaluation for respirator use in the substance specific standards so that they are in addition to medical surveillance requirements to identify any symptoms of disease potentially caused by exposure to the substance.

Workplace tests have not indicated that disposable respirators offer less protection than reusable respirators. There is no valid reason to exclude the use of disposables in any substance specific standard (such as asbestos, inorganic arsenic, etc.).

NIOSH does not have an approval schedule for coke oven emissions. AIHA recommends that 1910.1029(g)(2)(iii) be deleted.

AIHA recommends that the title of the subparagraph in Acrylonitrile 1910.1045 (h)(3)(iii) be changed to "Fit Testing" from "Testing" to maintain consistency in terminology.

AIHA recommends that the subparagraphs in Acrylonitrile 1910.1045 (h)(3)(iii)(A) and (B) be dropped and that issues of fit testing be addressed only in 1910.134 to maintain consistency of wording and application.

AIHA recommends that respirator requirements found in ventilation 1910.94(d)(11)(v) be revised to address the misuse of a hose mask with blower and a gas mask in emergencies where atmospheres may be IDLH or unknown.

AIHA recommends that requirements addressing the handling and storage of ammonia (1910.111(b)(10)(ii)) be clarified to say that 1910.134 applies and that gas masks are unacceptable for entry into IDLH, unknown, or oxygen deficient atmospheres.

AIHA recommends that 1910.252 (c)(4)(ii) should refer to 1910.134. Respirator selection should be based on exposure levels.

AIHA recommends that 1910.252 (c)(7)(iii) refer to 1910.1025 with its sampling requirements and respirator selection table to maintain consistency.

AIHA recommends that 1910.252 (c)(9)(i) refer to 1910.1027 (not 1910.1000) with its sampling requirements and respirator selection table to maintain consistency.

AIHA recommends that 1910.252 (c)(10) refer to 1910.134. Respirator selection should be based on exposure levels.

AIHA recommends that 1910.261 (b)(2) references should be to 1910.95, .132, .133, etc., rather than to out of date ANSI standards.

AIHA recommends that 1910.261 (g)(10) specify that gas masks are limited to escape only or entry into known concentrations below IDLH with adequate oxygen. AIHA also recommends that reference to an old ANSI standard be deleted.

54-208 B

ATTACHMENT I

The Assigned Protection Factor of Ten for Half Mask Respirators

Thomas J. Nelson
NIHS Inc., 2401 East Mall Ardentown DE 19810

A number of researchers have published or presented papers on workplace protection factor (WPF) studies involving half mask respirators. Individually, each study contains a relatively small amount of data, generally less than 25 data points for any single respirator. Because of the small amount of data, any attempt to quantify the result statistically does not provide useful information on the low end of the distribution of WPFs. Several studies on half mask respirators were combined to yield a data set with 390 observations. Of these WPF data, 1.5% were less than 10, the best estimate of the 5th percentile was 13 with a 95% confidence interval of 10 to 18. Differences between the mean WPF based on the type of filter were found, but no difference was found between the mean performance of elastomeric and disposable respirator equipped with dust/mist and dust/fume/mist filters.

Introduction

A number of studies have estimated the performance of half mask air purifying respirators through the use of workplace protection factor (WPF) studies[1,5-17]. One use of the information from these studies has been the assignment of protection factors.

The reported performance of half mask respirators for these studies has been in terms of the best estimate of the 5th percentile. Little use has been made of confidence intervals to better describe the uncertainty involved in these estimates. The problem in using confidence intervals is that the studies used to define performance have generated a relatively small amount of data with a large amount of variation. For example, in the Nelson and Dixon study of respirator performance during asbestos removal, the North respirator showed a mean protection factor of 245, with a geometric standard deviation of 6.5 [1]. The best estimate of the 5th percentile was 11 with 95% confidence limits of 1.1 to 37. It is obvious that this information by itself is not useful in setting an assigned protection factor since the range includes 1 or no protection assignable.

A second issue in assigning protection factors is how to group the widely varying styles and construction of masks. Within the group of half mask respirators, the ANSI Z88.2 committee combined elastomeric and disposable types into a single class, with an assigned protection factor of 10.[2] The type of filter or cartridge also does not change the assigned protection factor according to ANSI. Are there significant differences between these differing styles and constructions of masks that warrant different levels of assigned protection? The few studies that contain data with the differing styles and types of respirators do not contain enough data points that allow these questions to be answered. The WPF studies contain few data points because these studies are difficult to perform, require a large amount of manpower and money to collect each sample.

The technique of meta-analysis has been used to evaluate the information from clinical trials and used in epidemiology to increase the statistical power by combining the information from a number of related studies. To do such an analysis though requires several questions to be addressed:[3] Are all studies to be included or only published ones? Are all studies to be included or only the "good" ones? When the study results are heterogeneous, how may they be included in a meta-analysis, or should they be used at all?

In this analysis the data from published and unpublished studies on respirators have been reviewed. Each study was analyzed to determine if the research protocol used was similar and if flaws in study design and data collection existed which would not allow the information to be combined. Rather than a strict statistical analysis of data as would be done in a meta analysis, the data from similar studies were simply pooled into a single data set.

Studies Evaluated:

For this analysis, the studies on half mask air purifying respirators listed by Johnston *et al.* in their review article on performance testing were evaluated [4]. These include published and unpublished studies. A summary of the studies is provided in Table I, the unpublished studies are noted.

Dixon and Nelson studied the performance of a Survivair half mask respirator equipped with high efficiency particulate air (HEPA) filters in a lead chromate pigment production facility[5]. To qualify for the study, a person was required to pass an isoamyl acetate qualitative fit test. Eleven people participated in the study. The samples were collected for a single wearing of the respirator that lasted from 30 minutes to two hours. Samples were analyzed by proton induced x-ray emission (PIXE) for lead with a detection limit of approximately 10 ng per sample. The mass mean aerodynamic diameter of the particles was measured at 1.8 μm.

Gaboury and Burd studied the performance of Wilson, Survivair and American Optical half mask respirators equipped with organic vapor/acid gas cartridges and either dust/mist (DM) or dust/fume/mist (DFM) filters in a primary aluminum refinery[6]. They measured benzo-alpha-pyrene, contained in the benzene soluble materials present in the process. The analytical detection limit was 0.003 ug/m3. To qualify for the study, the person needed to pass a quantitative fit test with a minimum fit factor of 100. Twenty two people participated in the study. Because of the heat load in the production areas, workers spent one half hour each hour in a cool environment. The sampling was stopped during this time period. Therefore, each data point is a WPF for multiple wearings in each work shift. The mean particle size was less than 0.52 μm.

Lenhart and Campbell studied the performance of MSA half mask respirators equipped with HEPA filters in a primary lead smelter in the sinter plant and blast furnace

areas[7]. To qualify for the study a person was required to pass a quantitative fit test with a minimum fit factor of 250 required. The 25 workers who participated wore the respirators for as much of the 8 hour shift as possible, so the data represents a WPF for multiple wearings in each work shift. The lead was analyzed by atomic adsorption with a detection limit of 2 to 5 ug for the lapel samples and 0.2 μg for the in-mask samples. The mean aerodynamic particle diameter in the sinter plant was 9 to 16 μm, and 1-10 μm in the blast furnace area.

Reed *et al.* studied the performance of a 3M 9910 DM respirator in a concrete patching mixing and bagging area[8]. To qualify for the study a quantitative fit test was performed, to look for gross leakage. No minimum fit factor was given for inclusion in the study group. Seven people participated in the study. The mass collected inside and outside the respirators was determined by weighing after desiccation. The mean aerodynamic diameter of the particulate was measured at 8 to 20 μm depending on location within the worksite.

The Nelson and Dixon study was conducted during asbestos abatement operations with the 3M 8710 DM, 3M 9910 DM, Survivair half facepiece respirator with DFM and HEPA filters, and the North 7700 with HEPA filters[1]. To qualify for the study, the person needed to pass a saccharin qualitative fit test. Seventeen people participated in the study. Samples were collected for 30 minutes to two hours. Each WPF data point represented a single wearing. 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 of the method was approximately 0.0006 fibers/ml for a 100 liter sample, with a reliable limit of quantification of approximately 0.006 fibers/ml.

Gosselink *et al.* evaluated the performance of the 3M 8710 DM, 3M 9910 DM, 3M 9920 DFM and 3M 7000 series half facepiece respirator with HEPA or DM filters in a brake manufacturing facility[9]. To qualify for the study, the person needed to pass a saccharin qualitative fit test. Twelve people participated, samples were collected for approximately 0.5 hours. The asbestos fibers were counted using phase contrast microscopy, with a modification to increase the number of fields counted to increase sensitivity. The detection limit for the sample size collected inside the respirator (2 lpm, 0.5 hour) would have been about 0.001 fibers/ml based on the modified counting method.

Johnston and Mullins studied the performance of the 3M 8715 DM respirator in a metal fabricating facility[10]. The dusts analyzed were titanium, aluminum and silicon. Samples were collected for 35 to 235 minutes and included multiple wearings for a single WPF determination. The metals were analyzed by PIXE. To qualify for the study, the person needed to pass a saccharin qualitative fit test. Five subjects participated.

Colton and Mullins measured the performance of a maintenance free high efficiency respirator in a brass foundry[11]. The respirators were worn for 30 minutes to 4.5 hours, each sample a single wearing of a respirator. To qualify as a participant, each

person was required to pass a saccharin qualitative fit test. Seventeen people participated in the study. The samples collected outside the respirator were respirable dust samples. Dust and fume were both present. Depending on the area of the plant, 20 to 60% of the mass of the aerosol was greater than 10 μm. The samples were analyzed for lead and zinc by PIXE, with a level of quantification of less than 10 ng.

A study by Colton *et al.* was conducted in an aluminum smelter[12]. The respirator studied was a 3M 9906 with a DM filter. The samples collected outside the respirator were respirable dust. The samples were analyzed by PIXE, with a level of quantification less than 30 ng. To qualify as a participant, each person was required to pass a saccharin qualitative fit test. Workers were sampled for the duration of the task, so each data point represents a single wearing of the respirator. Twenty four workers were sampled over five days. The particle size analysis by a cascade impactor shows approximately 50% of the dust was greater than 10 μm in diameter.

Several studies not listed in the Johnston article were also evaluated [4]. These included a study by Colton and Mullins who determined WPFs for a DFM disposable respirator worn during welding and grinding operations[13]. Twenty employees wore the respirators. Samples were collected for 40 to 190 minutes, with four sample sets a day collected. Fit testing was done by the saccharin method. Samples were analyzed by PIXE for iron, magnesium, zinc and titanium. Particle size analysis showed both dust and fume were present.

Another study not listed was one by Galvin *et al.*[14] They studied the performance of a half mask respirator equipped with organic vapor cartridges in a styrene atmosphere. The samples were collected for three to six one hour periods for each of the thirteen people who participated in the study. To qualify for the study, the person needed to pass an irritant smoke qualitative fit test. Samples were analyzed by gas chromatography-flame ionization for styrene. The inside samples were corrected for lung retention.

A study by Myers[15] which is being prepared for publication was also evaluated. In this study, DM, DFM and HEPA filter respirators, with both disposable and elastomeric face pieces were studied in a variety of workplaces. These included three foundries, an aircraft painting facility and a steel mill. Fit testing was accomplished with a quantitative fit test for the elastomeric respirators and the saccharin qualitative fit test for the DM and DFM disposable respirators. The minimum fit factor required to pass the quantitative fit test was 100. Sixty-four people participated in the study. Samples were analyzed by PIXE for the inside samples and all outside samples except those from the steel mill. Because of the large amounts of material collected on the outside filters at the steel mill, the samples were analyzed by atomic absorption.

Wallis et. al. studied the performance of a 3M 8710 disposable respirator in a battery manufacturing facility [16]. Seventy samples were collected on a number of people in various areas of the operation. Employees were not trained nor fit tested during the

time of the study, but had prior training and fit testing. The samples were collected on cellulose ester filters and analyzed by atomic absorption. The detection limit was 0.004 to 0.006 mg/m^3, the concentration of manganese outside the respirator ranged from 0.14 to 77.4 mg/m^3. Area samples collected for particle sizing showed that more than 60% of the mass was greater than 10 μm in diameter the largest size selector used in the impactor. Less than 10% of the dust was smaller than 2 μm in diameter.

A recently reported WPF study by Pallay was not included in the analysis.[17] For this study, preliminary results have been reported at various meetings, but the data collected were not available.

Several of the very first half facepiece respirator studies such as those by Revoir[18], Moore and Smith[19] and Smith *et. al.*[20] were not included in this analysis since they were not WPF studies. They were effective protection factor studies, where in-mask sampling included the time while the respirator was not being worn. Also they were conducted before the more recently developed and validated fit test methods became available.

Analysis of the Studies

To be able to combine the data from several studies, the methods used to collect the WPF data needed to be evaluated to determine if they were similar enough in design and execution to allow them to be grouped. The portions of a WPF study that have an effect on the outcome include the test subjects familiarity with the respirator, motivation to participate, their training in proper fitting and use, the method of fit testing, and the methods for sample collection and analysis[4]. Training, familiarity with the respirator, motivation and proper use are variables which are generally described but cannot be objectively evaluated. Methods of fit testing and sample collection and analysis can be objectively evaluated.

Fit testing is an important variable. The protection factor is strongly dependent on the properties of the facepiece including how well the facepiece seals to the wearers face[21]. Fit testing determines which respirators are suitable. This is recognized by many standards, such as ANSI Z88.2 that require a fit test to select respirators[2]. The definition of a WPF also requires that the respirator be properly selected, fitted and tested[22].

To determine a WPF requires that the concentrations outside and inside the respirator be measured. Since a WPF is calculated as the ratio of these two concentrations, sample collection and analysis directly affect the WPF observed.

Analytical methods used need to be specific and accurate over a wide range of concentrations. A study of half mask respirators may result in WPF values from less than 10 to over 10,000 based on observed quantitative fit factors. The environment inside a facepiece is high in humidity and at a temperature near 35°C. The concentration inside

the facepiece will likely be 10 to 10,000 times lower than the ambient concentration, where the analytical method has been validated. The collection of samples from this environment must not be affected by these extreme conditions.

Studies Rejected Because of Inadequate Fit Tests

The study by Galvin *et al.* used the irritant smoke fit test as outlined in the ANSI Z88.2 (1980) standard [14]. The level of smoke that leads to a response by the person being tested is checked, but the concentration at which a response occurs is not known. Unlike the isoamyl acetate and saccharin fit tests[23], the level of irritating smoke generated during a test has not measured with the specific protocol. Both the saccharin [24] and the isoamyl acetate test protocols [25] have been studied and experiments have verified the concentrations for the taste or odor sensitivity and the test concentration.

In the study by Reed *et. al.* the quantitative fit test used was not appropriate for the respirator being used[8]. An oil mist quantitative fit test requires the use of HEPA filters so that face seal leakage can be separated from filter leakage. In this study, the respirator had a DM filter. In addition, the analytical method was a mass determination by weighing. Since the material being measured was a cement product, the inside the mask samples would have been in a humid environment and would include moisture that would be chemically reacted in the cement matrix. In addition, the test is not specific, other material such as sweat and sputum collected on the filter would also be included in the inside mass. These factors would bias the inside the respirator samples, increasing filter weights, and decreasing the observed WPF.

Studies Rejected Because of Inadequate Concentration Measurements

In the WPF study by Johnston and Mullins, a relationship between the mass of the analyte outside the respirator and the WPF value was found[10]. It appears that in the workplace studied, the concentration of the contaminants was so low as to affect the WPF results seen. In their data they used a cut-off point of at least ten times the mean blank value, but suggest that a value of 100 be used as a minimum. The review article by Johnston also recommends that the outside sample weight equal at least ten times the assigned protection factor time the mean field blank[4]. For a half mask this would equal a value of 100. Because the low outside concentrations had an effect on the WPF measured, this study was eliminated from the analysis.

In the Colton and Mullins study, the outside the respirator samples were collected as respirable dust samples[11]. Myers *et. al.* have shown using transmission electron microscopy that large particles do penetrate inside the respirator facepiece[26]. Collecting outside the respirator samples as respirable dust samples will bias the observed WPF, making the WPF appear lower than actual if a large part of the material in the workplace is removed by the cyclone. Depending on the area of the plant, 20 to 60% of the mass of the aerosol was greater than 10 μm and would not be collected by the cyclone.

In the Colton *et. al.* study at an aluminum smelter, respirable dust samples were again collected as outside samples[12]. Impactor data collected during the study suggests that approximately 50% of the dust present was not collected on the outside samples. Therefore the outside samples will bias the observed WPF seen, making them appear lower than actual.

In the Wallis study several points need to be examined [16]. First the C_o and C_i samples were collected by different methods. The C_i samples were collected by probing the respirator with a sample inlet designed by Liu[27] to minimize sample loss at the inlet. In contrast the C_o samples were collected with a closed face and the Liu probe was not used. This will cause the outside samples to underestimate the concentration of manganese. As shown by Liu a similar designed inlet would have almost 30% of the particles larger than 10 μm deposited in the inlet compared to almost no deposition with the Liu probe. The authors point out that the concentration outside the respirator were related to the WPF found. For all data points, the best estimate of the 5th percentile was 7.5, when only data for C_o samples greater than 100 times the detection limit are used, the 5th percentile is 10.8; when data 1000 times the detection limit are used (5 mg), the 5th percentile is 35.

Acceptable Studies

The following studies are included in the analysis. They included an acceptable qualitative fit test with a protocol that is based one listed in the OSHA lead standard[23] or a quantitative fit test. The analytical methods employed were specific and the ratio of the outside concentration to the detection limit was in each case 100 or more.

In the Lenhart and Campbell study, the ratio of the outside concentration to the detection limit of the analyte was at least 40, and averaged well over 100 [7]. The lowest outside mass value reported was 92 $\mu g/m^3$, with a detection limit of 2 $\mu g/m^3$, the lowest ratio was 46 (based on a sample time of 8 hours at 2 lpm with a detection limit reported at 2 ug/m^3). Fit testing was by a recognized quantitative fit test method. The required fit factor to be included in the study was 250, which is higher than the other studies under consideration. The effect of this higher fit factor on the observed WPF's is unknown. However fit factors have not been shown to be a predictor of WPFs [5,27].

In the Dixon and Nelson study, the ratio of the outside concentration to the detection limit was well above 100 (the average outside concentration was 225 μg/m3, based on a one hour sample time and the detection limit, the lowest concentration that could be measured was approximately 0.1 $\mu g/m^3$)[5]. Fit testing was done using the isoamyl acetate fit test. The in-mask samples were collected without the probe designed by Dr. Liu [28] that was designed to minimize sample loss on the probe surfaces. The effect of the use of a non-Liu designed probe on the sample results is unknown since most of the particles where of the size range were the probe design has less of an effect on deposition.

In the Gosselink *et. al.* study, the average asbestos fiber concentration was 2.21 fibers/cc, approximately 100 times the detection limit of 0.02 fibers/cc[9]. Fit testing was with the Saccharin protocol[23]. In the Nelson and Dixon study with asbestos, the median fiber concentration was 2.6 fibers/cc outside the respirator approximately 100 times the detection limit of 0.02 fibers/cc[1]. Fit testing was with the saccharin protocol[23]. In both studies the closed face sampling technique was verified to not have adversely effected the deposition of fibers on the filter surface by a comparison of closed face and open faced sampling. Nelson and Dixon also measured the deposition of fibers on the filter which was zoned into three concentric and equal areas (outer, middle, inner). For both closed and open faced samples, the fiber density was not significantly different among the zones.

In the Gaboury and Burd study, the ratio of benzo-alpha-pyrene was more than 2500 times the average concentration outside the respirator (detection limit of 0.003 μg/m3 versus an average concentration of 7.97 μg/m3)[6]. Fit testing was done using a quantitative fit test method with a minimum fit factor of 100.

In the Colton and Mullins study during welding, samples were analyzed for zinc, titanium, magnesium and iron[13]. For zinc, the inside concentration ranged from 0.1 to 9.7 $\mu g/m^3$. Outside the respirator samples, concentrations were from 4.2 to 1062 $\mu g/m^3$. With a detection limit of approximately 15 ng/ filter or approximately 0.05 ug/m^3, the concentration outside the respirator averaged well over 100 times the detection limit. The WPF values for zinc were used in the analysis purely for convenience.

In the Myers *et. al.* study, the mean concentration inside the respirator was well above 100 times the detection limit [15]. For example, the concentration of zinc outside the respirator in the first study site was 12.2 to 629 ug/m^3. The detection limit was approximately 0.08 ug/m^3 for a two hour sample. In the foundry portion of the study, the outside samples were collected as respirable dust samples, however these were corrected to yield total dust weights and these data were used in the calculation of the WPF's. For the other study sites, total dust samples were collected on outside samples. Fit testing was by either the saccharin qualitative fit test[23] or a quantitative fit test with minimum fit factor of 100 required.

Results of the analysis

Using the WPF results from the included studies, geometric means (GM), geometric standard deviations (GSD) and the best estimates of the 5th and 95th percentile were calculated using LOGAN [28]. These values are shown in Table II. A plot of the geometric mean, 5th and 95th percentiles from each included study show that the studies resulted in comparable ranges of WPF measurements (Figure 1). Since the studies cover comparable ranges of data, they were combined into a single data set.

This resulted in 390 data points. Of these 390 data points, six WPF values, or 1.5% of samples were less than ten. A log probability plot of the data is shown in Figure

2. The geometric mean is estimated at 290, with a GSD of 6.5. The best estimate of the 5th percentile is 13, with 95% confidence interval of 10 to 18. This is consistent with the assigned protection factor of 10 listed by the ANSI Z88.2 (1992) standard[2].

A one way analysis of variance of these data separated into categories by filter type showed there was a significant difference among the mean WPFs with a p-value less than 0.00001 (Table IV). Using an α of 0.001 a multiple t confidence interval was calculated to determine which types of filters were significantly different [29]. The mean performance of respirators equipped with HEPA filters was found to be significantly higher than the respirators equipped with either a DM or DFM filters. The mean WPF for the respirators equipped with DM filters was significantly higher than that for the respirators with the DFM filters.

Next the data were grouped and analyzed according to respirator type: elastomeric or disposable. Since there were significant differences between filter types, each filter type was examined separately. For the DM filter types, elastomeric respirators were used in the Gaboury (4), Gosselink (8) and Myers (30) studies; disposable respirators were used in the Nelson (32), Gosselink (22) and Myers (21) studies. For the DFM filter types, elastomeric respirators were used in the Gaboury (14), Nelson (15) and Myers (46) studies; disposables in the Gosselink (8), Myers (20) and Colton welding (32) studies. Table V and VI summarize the statistical parameters for the respirators equipped with the two types of filters. A student's t-test shows that the WPFs do not differ between mask types with a P(two tailed) of 0.54 for the DM and 0.25 for the DFM.

A comparison cannot be made for HEPA filter respirators since there are no disposable HEPA filtered respirators included in this analysis.

Conclusion

The ANSI Z88.2(1992) standard defines the assigned protection factor as "the minimum 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"[2]. The assigned protection factor for half mask respirators is 10. For the studies examined in this analysis, the 5th percentile of WPFs was 13 with the lower 95% confidence interval of 10. This appears to support the assigned protection factor for this class of respirators.

This conclusion is based on the combination of data from a number of studies which are assumed to be similar. Many factors can affect the data collected during a WPF study, several of these factors cannot be objectively evaluated such as the level of motivation of a subject participating in a study. As noted by Johnston, many studies have been reported at professional and scientific meetings, but not yet published in the literature.[4] This required that a critical review be performed with these before they were included with the published studies.

When type of filter was examined, the mean WPF for respirators equipped with HEPA filters is significantly higher than that for respirators equipped with either DM or DFM filters; and the respirator equipped with DM filters have a significantly higher mean WPF than the respirators equipped with DFM filters.

Leakage into a respirator will be governed by several factors including filter efficiency, face seal leakage and leakage through defects such as a faulty valve. Depending on the particle size of an aerosol, a respirator with a HEPA filter may be expected to perform better than a respirator with either a DM or DFM filter.

Campbell[21] predicts that a comparison of two filters, one with higher particle penetration and lower filter resistance will have a GM WPF value that is higher than the other filter. He compared a filter with a penetration of 0.001 and a resistance of 25 mm (Hg) to a filter with a penetration of 0.003 and resistance of 10 mm (Hg), and predicted GM protection factors of 70 and 106 respectively. A DM filter may have higher filter penetration and lower filter resistance when compared to a DFM filter which would explain in part the difference in the mean WPF found in these studies .

When the differing styles of respirators are examined, the disposable respirators have a mean WPF that is not significantly different from that for the elastomeric respirator equipped with either DM filters and DFM filters. Therefore there appears to be no reason to assign different assigned protection factors to the two types of mask construction, elastomeric and disposable for these two types of filters.

The performance of a DM, DFM and HEPA filters when comparing the 5th percentiles are not that different and are not inconsistent with the assigned protection factor of 10. If the assigned protection factor was based on an average level of protection, then the differences seen would be significant. Other factors will effect the protection a respirator provides, such as wear time (which is not considered in WPF studies). Wear time may be affected by comfort, employee motivation and other factors. These other factors are further reasons why a higher assigned protection may not be reasonable even though differences in mean performance have been seen.

Acknowledgments

The Author wishes to thank Warren Myers and Craig Colton for providing access to the data in their studies and support in preparing the article.

1. **Nelson, T. J. and S. W. Dixon:** "Respirator Protection Factors for Asbestos, Parts I and II." Paper presented at the 1985 American Industrial Hygiene Conference, Las Vegas, Nevada (May 23, 1985).
2. ANSI Z 88.2 (1992), American National Standard for Respiratory Protection, American National Standards Institute, 11 West 42nd Street, New York, New

York 10036

[3]. **Fleiss, Joseph L. and Alan J. Gross**: Meta-analysis in Epidemiology , with Special Reference to Studies of the Association Between Exposure to Environmental Tobacco Smoke and Lung Cancer: A Critique. J Clin Epidemiol. Vol 44. No2: 127-139 (1991)

[4]. **Jonhston A.R., W.R. Myers, C.E.Colton, J.S.Birkner, C.E. Campbell**: Review of Respirator Performance Testing in the Workplace. Issues and Concerns. Am. Ind.Hyg Assoc. J. 53(11):705-712 (1992)

[5]. **Dixon, S.W. and T. J. Nelson**: Workplace Protection Factors for Negative Pressure Half-Mask Facepiece Respirators. J. Int. Soc. Respir. Prot. 2(4):347-361(1984).

[6]. **Gaboury, A. and D. H. Burd**: "Workplace Protection Factor Evaluation of Respiratory Protective Equipment in a Primary Aluminum Smelter." Paper presented at the International Society for Respiratory Protection Conference, San Francisco, CA (November 1989).

[7]. **Lenhart, S.W. and D. L. Campbell**: Assigned Protection Factors for Two Respirator Types Based Upon Workplace Performance Testing. Ann. Occup. Hyg. 28(2):173-182 (1984).

[8]. **Reed, L.D., S.W. Lenhart, R.L.Stephenson, and J.R. Allender**: Workplace Evaluation of a Disposable Respirator in a Dusty Environment. Appl. Ind. Hyg. 2(2):53-56(1987)

[9]. **Gosselink, D. W., D. P.Wilmes, and H. E.Mullins**: "Workplace Protection Factor Study for Airborne Asbestos." Paper presented at the American Industrial Hygiene Conference, Dallas, Texas (May 1986).

[10]. **Johnston, A. R. and H. E. Mullins**: "Workplace Protection Factor Study for Airborne Metal Dusts." Paper presented at the 1987 American Industrial Hygiene Conference, Montreal, Canada (June 4, 1987).

[11]. **Colton, C. E. and H. E. Mullins**: "Workplace Protection Factor Test Brass Foundry." Paper presented at the 1990 American Industrial Hygiene Conference, Orlando, Florida (May 1990).

[12]. **Colton, C. E., A. R. Johnston, H. E. Mullins, C. R. Rhoe and W. Myers**: "Respirator Workplace Protection Factor Study on a Half Mask Dust/Mist Respirator." Poster presented at the 1990 American Industrial Hygiene Conference, Orlando, Florida (May 17, 1990).

[13]. **Colton, C. E.and H. E. Mullins**: "Workplace Protection Factors for a Half Mask Dust/Mist/Fume Respirator." Poster presented at the 1992 American Industrial Hygiene Conference, Salt Lake City, Utah (May 17, 1992).

[14]. **Galvin K., S. Selvin, and R. C. Spear**: Variability in Protection Afforded by Half-Mask Respirators Against Styrene Exposure in the Field. Am. Ind. Hyg. Assoc. J. 51:625-639(1990).

[15]. Warren Myers, Discussion of Preliminary Data, NPCA Respirator Study April 23, 1990(Private Conversation).Dr. Warren Myers, University of West Virginia, P.O. Box 6101, Morgantown WV 26506

[16]. **Wallis G., R. Menke and C. Chelton**:Workplace Field Testing of a Disposable Negative Pressure Half-Mask Dust Respirator (3M 8710). . Am. Ind. Hyg. Assoc. J. 54(10):576-583 (1993)

[17]. **Pally, B., J. Gamble, L. Jerman, J. Allender, P. Hewett, M. Petersen, and J. Stevens**: "Workplace Protection Factor (WPF) Study of Particulate Air Purifying respirators at Lead acid Battery Manufacturing Facilities." Paper presented at the American Industrial Hygiene Conference, Orlando Fla., May 1990.

[18]. **Revoir, W.H.**: "Respirators for Protection Against Cotton Dust". Am. Ind. Hyg. Assoc. J. 35(8):503-510 (1974)

[19]. **Moore, D.E. and T.J.Smith**: Measurement of Protection Factors of Chemical Cartridge, Half Mask Respirators under Working Conditions. Am. Ind. Hyg. Assoc. J. 37(8):453-458 (1976)

[20]. **Smith T.J., W.C. Ferrell, M.O. Varner, and R.D. Puttnam**: Inhalation Exposure of Cadmium Worker Effects of Respirator Use. Am. Ind. Hyg. Assoc. J. 41(9): 624-629 (1980)

[21]. **Campbell D. L.**: The Theoretical Effect of Filter Resistance and Filter Penetration on Respiratory Protection Factors. J. Int. Soc. Respir. Prot. 2(4):198-204(1984)

[22]. American Industrial Hygiene Association Respiratory Protection Committee: Respirator Performance Terminology. [Letter to the Editor]. Amer. Ind. Hyg, Assoc., J. 46(5):B22-B-24 (1985)

[23]. "Occupational Safety and Health Standards", *Code of Federal Regulations* Title 29 Part 1910 (1910.1000 to end) 1990 pp. 156-194

[24]. **Marsh J. L.**:Evaluation of Saccharin Qualitative Fitting Tests for Respirators. Am. Ind. Hyg. Assoc. J. 45(6): 371-376 (1984)

[25]. **Nelson T. J., O. T. Skretvedt, J. G. Loschiavo and S. W. Dixon**: Development of an Improved Qualitative Fit Test Using Isoamyl Acetate J. Int. Soc. Respir. Prot. 2(4):225-248(1984)

[26]. **Myers W. A., Z. Zhuang, T. Nelson, S. Sides and D. Wilmes**: Field Performance Measurements of Half Facepiece Respirators- Study Protocol.Am. Ind. Hyg. Assoc. J. (In Press)

[27]. **Liu, B. Y. H., K.L. Dega, K.L. Rubow, S. W. Lenhart and W. R. Myers**: In - mask Aerosol Sampling for Powered Air Purifying Respirators. Am. Ind. Hyg. J. 45(4): 278-283(1984)

[28]. Logan, Workplace Exposure Evaluation System, (Computer Software) American Industrial Hygiene Association, 1990

[29]. **Dowdy, S. and S. Wearden**: Statistics for Research, 2nd. ed.. New York, N.Y.: John Wiley and Sons, 1991. pp321-323

Table I
Summary of the Studies

Study	Respirator type	Filter type	Fit test	Analyte	Analytical method	Detection limit	Lin Probe	#People	Particle size (mean)
Dixon	Elastomeric	HEPA	Isoamyl	Lead	PIXE	2 ng sample	No	11	1.8 µm
Gaboury ^	Elastomeric	DM DFM	Quantitative (100 min FF)	BAP	HPLC	0.003 µg/m3	Yes	22	< 0.52 µm
Lenhart	Elastomeric	HEPA	Quantitative (250 min FF)	LEAD	AA	0.2 µg sample (inside resp.)	Yes	25	9-16 µm or 1-10 µm
Reed	Disposable	DM	Quantitative (min FF not given)	Cement dust	Mass	0.01 mg sample	Yes	7	8- 20 µm
Nelson ^	Disposable Elastomeric	DM, DFM, HEPA	Saccharin	Asbestos	Fiber count	0.0006 fibers/ml	Yes	17	0.49 um
Gosselink ^	Disposable Elastomeric	DM, DFM HEPA	Saccharin	Asbestos	Fiber count	0.001 fibers/ml	Yes	12	-
Johnston ^	Disposable	DM	Saccharin	Ti, Al, Si	PIXE	9-35 ng per sample	Yes	5	--
Colton- brass ^	Disposable	HEPA	Saccharin	Pb, Zn	PIXE	< 10 ng per sample	Yes	17	Dust and fume both present
Colton - Al ^	Disposable	DM	Saccharin	Al	PIXE	< 10 ng per sample	Yes	5	~ 10 um
Galvin	Elastomeric	Charcoal cartridge	Irritant smoke	Styrene	GC	1µg/sample	No	13	--
Myers -foundries ^	Elastomeric Disposable	DFM	Saccharin, quantitative (min 100 FF)	Zn, Pb	PIXE	< 10 ng per sample	Yes	25	Dust and fume both present
- aircraft ^	Elastomeric	HEPA	quantitative (min FF 100)	Ti, Cr	PIXE	< 10 ng per sample	Yes	22	-
- steel mill ^	Elastomeric Disposable	DM	Saccharin	Fe	PIXE, AA	< 10 ng per sample	Yes	17	Dust and fume both present
Colton- welding ^	Disposable	DFM	Saccharin	Fe, Mg, Zn, Ti	PIXE	<10 ng/sample	Yes	20	Dust and fume both present
Wallis	Disposable	DM	Saccharin	Mn	AA	0.004-0.006 mg/m³ as Mn	Yes C_1 No C_2	---	~ 60% > 10 µm

^ Studies that have not been published

Table II
Summary of Study Parameters

Studies included in the analysis

Study	N	GM	GSD	5th percentile	95th percentile
Dixon	42	3360	4.8	254	44400
Gaboury [A]	18	47	2.5	10	210
Lenhart	25	166	3.8	18	1500
Nelson [A]	76	258	5.2	17	3900
Gosselink [A]	44	96	2.3	24	390
Colton-welding [A]	32	147	2.5	33	660
Myers [A]	153	346	7.2	14	8800

Studies **not** included in the analysis

Study	N	GM	GSD	5th percentile	95th percentile	Reason not included
Reed	19	18	3.17	2.7	120	Non specific analytical, biased inside samples, QNFT not HEPA filters
Johnston [A]	18	44.8	2.85	8	251	Low inside the facepiece weights
Colton -brass foundry [A]	38	28.2	2.06	8.6	92	Outside samples biased
Colton- Al smelter [A]	42	469	3.87	50	4338	Outside samples biased
Galvin	63	75	3.1	11.7	482	Used unvalidated QLFT
Wallis	70	50	3.5	7.5	400	Biased and low outside concentrations

[A] Studies that have not been published

Table III
WPF Data For Filter Type.

Study	Dust-mist		Fume		HEPA	
	Number	GM	Number	GM	Number	GM
Gaboury	4	48	14	46	—	—
Lennart	—	—	—	—	25	166
Nelson	32	428	15	183	29	177
Dixon	—	—	—	—	42	3356
Gosselink	22	93	8	233	6	56
Myers	51	260	66	144	36	3983
Colton	—	—	32	146	—	—

Table IV
Analysis of Variance for Filter Type

	N	Avg (as Log_{10})	SD
Dust/Mist	117	2.32	0.35
Dust/Fume/Mist	135	2.08	0.34
HEPA	138	2.96	0.88

	SS	df	MS	F	p	F_{crit}
Between filters	56	2	28	52.28	>0.0001	3.51
Within Filters	208	387	0.54			

Where N = number of data, SD = standard deviation, Avg = mean, SS = sum of squares, df = degrees of freedom, MS = mean square, F= F statistic, p = probability

Table V
Comparison of Elastomeric and Disposable Respirators With DF Filters.

	Elastomeric	Disposable
Number	42	75
GM WPF	191	224
GSD	3.75	4.05
5th perct.	21.7	22.4
95th perct.	1680	2240

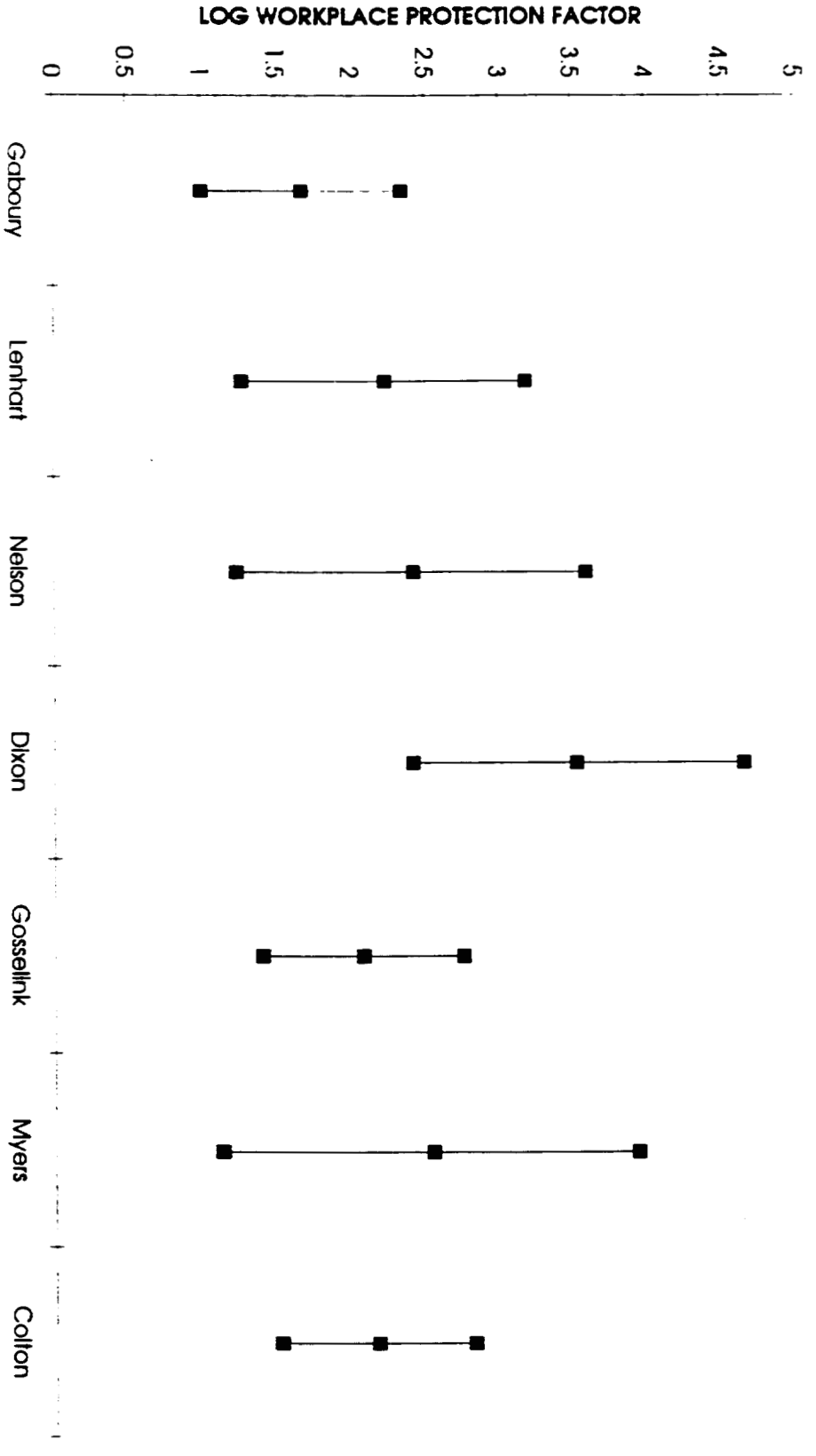
Table VI
Comparison of Elastomeric and Disposable Respirators With DFM Filters

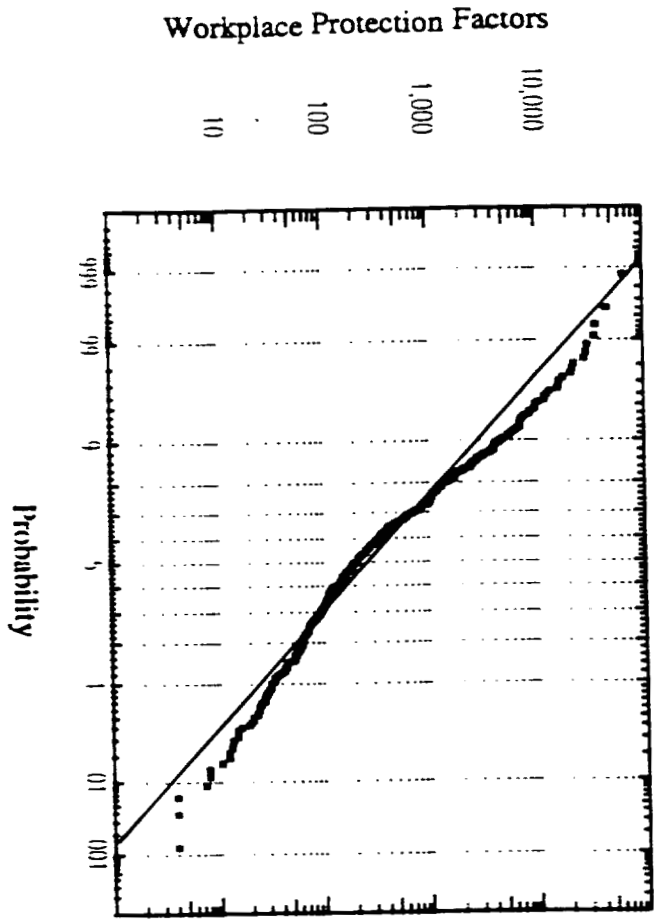
Study	Elastomeric	Disposable
Number	75	60
GM WPF	107	141
GSD	4.4	3.3
5th perct.	9.5	19.4
95th perct.	1210	1020

List of Figure Captions

Figure 1. Range of 5th percentile, geometric mean, 95th percentile

Figure 2. Probability plot of combined data set


LOG WORKPLACE PROTECTION FACTOR
5
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
Gaboury
Lenhart
Nelson
Dixon
Gosselink
Myers
Colton


10,000
1,000
100
10
Workplace Protection Factors
.001
.01
.1
.5
.9
.99
.999
Probability