54-263

CHEMICAL MANUFACTURERS ASSOCIATION

M.L. Mullins
Vice President-Regulatory Affairs

April 14, 1995

Docket Office
U.S. Department of Labor
Occupational Safety and Health
Administration
Room N-2625
200 Constitution Avenue, N.W.
Washington, D.C. 20210

OSHA
DOCKET OFFICER
DATE APR 14 1995

Attention: Docket H-049

Re: Respiratory Protection; Proposed Rule

Dear Sir or Madam:

The Chemical Manufacturers Association (CMA) is pleased to submit these comments on the Occupational Safety and Health Administration's (OSHA) proposed rule on respiratory protection (59 Federal Register 58884, November 15, 1994). CMA is a non-profit trade association whose members represent over 90 percent of the United States' productive capacity for basic industrial chemicals. CMA is vitally interested in this proposed rule because many of its member companies will be subject to its requirements.

CMA supports efforts by OSHA to improve its respiratory protection standard. The 1969 version of the American National Standards Institute's (ANSI) respiratory protection standard was the basis for the current standard. Respiratory protection technology has changed substantially in the past twenty-five years.

We have reviewed OSHA's proposed rule and have the following general comments:

- OSHA should demonstrate adequate assessment of risk and benefit to support this rulemaking. OSHA's proposed rule is based on a risk assessment that is not well documented.

- OSHA should define "hazardous exposure level" to mean airborne concentrations above the permissable exposure limit (PEL). OSHA should allow employers flexibility in determining which exposure limit to use when no PEL exists for a chemical.

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- OSHA should justify the need for requirements that are to be repeated periodically.

- OSHA should adopt a performance standard that minimizes unnecessary documentation. CMA supports the American National Standard for Respiratory Protection [ANSI Z88.2 (1992)].

CMA also has specific comments on several aspects of the proposed rule. We believe that many of OSHA's proposed requirements have not been adequately explained or justified in this rulemaking record. These specific comments are detailed within these comments.

If you have any questions regarding the attached comments, please contact Karen M. Cragg of my staff at (202) 887-1384.

Sincerely,

M.L. Mullins
Vice President-Regulatory Affairs

Attachment

54-263A

BEFORE THE
UNITED STATES OCCUPATIONAL SAFETY AND HEALTH
ADMINISTRATION

COMMENTS OF THE CHEMICAL MANUFACTURERS ASSOCIATION ON OSHA'S PROPOSED RULE ON RESPIRATORY PROTECTION

Comments on the Occupational Safety and Health Administration's Proposed Rule on Respiratory Protection, 59 Federal Register 58884, November 15, 1994.	)))))	OSHA Docket No. H-049

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I. INTRODUCTION

The Chemical Manufacturers Association (CMA) is pleased to submit these comments on the Occupational Safety and Health Administration's (OSHA) proposed rule on respiratory protection (59 Federal Register 58884, November 15, 1994). CMA is a non-profit trade association whose members represent over 90 percent of the United States' productive capacity for basic industrial chemicals. CMA is vitally interested in this proposed rule because many of its member companies will be subject to its requirements.

CMA supports efforts by OSHA to improve its respiratory protection standard. The 1969 version of the American National Standards Institute's (ANSI) respiratory protection standard was the basis for the current standard. Respiratory protection technology has changed substantially in the past twenty-five years.

We have reviewed OSHA's proposed rule and have the following general comments:

- OSHA should demonstrate adequate assessment of risk and benefit to support this rulemaking. OSHA's proposed rule is based on a risk assessment that is not well documented.

- OSHA should define "hazardous exposure level" to mean airborne concentrations above the permissible exposure limit (PEL). OSHA should allow employers flexibility in determining which exposure limit to use when no PEL exists for a chemical.

- OSHA should justify the need for requirements that are to be repeated periodically.

- OSHA should adopt a performance standard that minimizes unnecessary documentation. CMA supports the American National Standard for Respiratory Protection [ANSI Z88.2 (1992)].

CMA also has specific comments on several aspects of the proposed rule. We believe that many of OSHA's proposed requirements have not been adequately explained or justified in this rulemaking record. These specific comments are detailed within these comments.

II. GENERAL COMMENTS

A. OSHA Should Demonstrate Adequate Assessment Of Risk And Benefit To Support This Rulemaking. OSHA's Proposed Rule Is Based On A Risk Assessment That Is Not Well Documented.

CMA supports OSHA's efforts to update its respiratory protection standard. The current rule is based on respiratory protection technology that is twenty five years old. However, OSHA should demonstrate adequate assessment of risk and benefit to support this rulemaking. OSHA's proposed rule is based on a risk assessment that is not well documented.

In its preamble, OSHA makes the following statement of risk reduction that lacks documentation:

> "...Based on data found in the OSHA Integrated Management Information System (IMIS), OSHA determined that there is an annual average of 66,500 illnesses that are due to acute exposures to airborne hazardous substances. OSHA estimated that compliance with the existing standard could have prevented about 20 percent of these incidents, and that the proposed revisions to the existing standard could prevent an additional 5 to 10 percent. Thus, full compliance with proposed revisions to the existing standard could prevent between 3,325 and 6,650 illnesses due to acute exposures annually.
>
> In addition, using an Office of Technology Assessment estimate that 5 percent of all cancers are occupationally related, OSHA estimated that there are annually between 9,085 and 15,660 new cancer cases, between 6,850 and 11,000 cancer deaths, due to chronic exposures to occupational airborne carcinogens. In addition, airborne exposure to hazardous substances such as silica are estimated to account for another 4,200 chronic illnesses annually. OSHA anticipates that full compliance with the existing standard would prevent about 10 percent of these cases, and that proposed revisions to the existing standard would prevent an additional 2.5 to 5 percent. Thus, after a period of time, between 227 and 783 new cancer cases, between 171 and 550 cancer fatalities, and between 105 and 210 chronic illnesses could be prevented each year by full compliance with the proposed revisions to the respirator standard."

This statement forms the basis for the benefits OSHA expects to achieve by revising the current respiratory protection standard. However, OSHA does not provide adequate rationale for any reduction in adverse health effects due to the issuance of a revised standard. It is important to note that OSHA's risk reduction estimates focus not only on the proposed standard, but also on better implementation and enforcement of the existing one.

Centaur Associates' "Preliminary Regulatory Impact Analysis of Alternative Respiratory Protection Standards" (Exhibit 34) contains an analysis of workplace studies with respirators. The report concludes that a 100 to 200% improvement in respirator performance would result if respirators

were selected properly and minimal programs were instituted. This appears to form the basis for OSHA's estimate of risk reduction.

In order for OSHA to conclude that improvements in respirator performance will result in decreased adverse health effects, they must (1) show that exposures are excessive when respirators are being used improperly and (2) demonstrate that the individual program defects actually lead to a decrease in performance in these instances.

We agree that properly selected, fitted and used respirators will perform better than respirators that are not selected, fitted or used properly. It does not necessarily follow, though, that improved fit testing will lead to large improvements in overall performance. For example, fit testing is important to identify those employees who may not achieve adequate respirator performance. However, fit testing alone may not necessarily increase the performance of the respirator they use. The experience of many CMA member companies is that employees being fit tested normally achieve an adequate fit on the first try. Also, all respirator users do not need the full capability of the respirator being worn. A protection factor of two is sufficient for someone using the respirator 1.5 times the exposure limit.

B. OSHA Should Define "Hazardous Exposure Level" To Mean Airborne Concentrations Above The PEL. OSHA Should Allow Employers Flexibility In Determining Which Exposure Limit To Use When No PEL Exists For A Chemical.

OSHA should define "hazardous exposure level" to mean airborne concentrations above the PEL. OSHA should allow employers flexibility in determining which exposure limit to use when no PEL exists for a chemical rather than requiring the use of the threshold limit value (TLV) or recommended exposure limit (REL). OSHA should not establish a defacto standard setting process by requiring the use of the TLV or REL without allowing public input into the process.

While we support the use of exposure limits other than PELs, we do not believe that it is necessary for the employer to set exposure limits in each case. We support the language in ANSI Z88.2 (1992) that says the employer should:

> "Determine whether there is a published TLV, PEL, 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, yet the process of setting an exposure limit for these materials is not simple. ANSI acknowledges this and requires that an estimate of toxicity be made, allowing professional judgment to be used.

Under the existing standard, respirator use decisions are made on a voluntary basis. Professional judgment is used to determine which respirator will be acceptable. Estimates of toxicity and exposure limits from many sources are used in this process. In most instances, the choice of a respirator is based on its intended use rather than specific limits and air concentration measurements. For example, during the first entry into a pipe or piece of equipment, an air supplied respirator will be specified. Estimates of toxicity and exposure are appropriate to assess the validity of the respirator for the specified use.

C. OSHA Should Justify The Need For Requirements That Are To Be Repeated Periodically.

OSHA should justify the need for requirements that are to be repeated periodically. OSHA proposes that a number of requirements, such as training, medical evaluations and program evaluations, be repeated periodically. However, no adequate basis is given for the need to repeat these provisions at such a frequency. Some of the more burdensome requirements are described below.

First, OSHA proposes that respirators be cleaned and disinfected after each use. We agree that this is appropriate for respirators being used by more than one person. However, the requirement may be excessive when the respirator is assigned to a single user. The need for cleaning will depend on the environment in which it is worn and how long and often it is used. We suggest that the following performance language from ANSI Z88.2 (1992) be used to set a cleaning and disinfecting schedule:

> 4.5.7 Maintenance, Inspection, and Storage
>
> Maintenance shall be carried out according to the manufacturer's instructions and on a schedule that ensures that each respirator wearer is provided with a respirator that is clean, sanitary, and in good operating condition. Each respirator shall be inspected by the wearer prior to its use to ensure that it is in proper working condition.

Second, OSHA is proposing that training be given annually. We agree that initial training in respirator use is necessary, but we disagree that the complete respirator training program listed in the standard is needed on an annual basis for all respirators. Rather, we propose that the employee be given refresher training or asked to demonstrate the ability to use the equipment.

Finally, OSHA proposes that an annual assessment of the respirator program be conducted. We agree that some sort of assessment is needed, but do not believe that it needs to be an annual requirement. For simple programs such as a single air purifying respirator in use with a single contaminant, assessments might be necessary once every three to five years. For programs with numerous hazards that change repeatedly such as batch processes, reviews may be needed more frequently. We suggest that the following performance language from ANSI Z88.2 (1992) be used as an assessment requirement:

> Periodic Assessment
>
> The program shall be periodically audited to ensure that it is implemented and reflects the written procedures.

D. OSHA Should Adopt A Performance Standard That Minimizes Unnecessary Documentation. CMA Supports ANSI's Z88.2 (1992).

OSHA should adopt a performance standard that minimizes unnecessary documentation. OSHA has placed requirements for documented assessments in several sections of the standard that are unnecessary and overly burdensome.

For example, OSHA is proposing a program assessment that requires written summaries of each of the program requirements. Many of these are already written requirements and therefore it is redundant to document their content in an assessment. As stated earlier, we suggest that the following performance language from ANSI Z88.2 (1992) be used for program assessment:

> Periodic Assessment
>
> The program shall be periodically audited to ensure that it is implemented and reflects the written procedures.

Similar to ANSI Z88.2 (1992), OSHA should require employers to consider relevant factors in selecting an appropriate respiratory protection mechanism, but should not require documentation of inapplicable information. In many instances it may not be necessary to document each and every aspect of an exposure to select a respirator. For exposure to a nuisance dust during a loading operation, an industrial hygienist can easily understand the effect of each of the items listed by OSHA in order to select the appropriate dust respirator without the need to document that each item was obtained.

III. SPECIFIC COMMENTS

Section (a) Scope and application

OSHA Should Require Employees To Use The Provided Respiratory Protection In Accordance With The Employer's Policies, Instructions And Training.

OSHA should require employees to use the provided respiratory protection in accordance with the employer's policies, instructions and training. OSHA currently requires this, but has not included such language in its proposed rule. Centaur Associate's report (Exhibit 34) concludes that respirator performance would be improved by ensuring that employees wear respirators appropriately. We urge OSHA add to add the following language to the proposal:

> The employee shall use the provided respiratory protection in accordance with instructions and training received.

Section (b) Definitions

OSHA Should Modify Its Definition Of "Adequate Warning Properties."

OSHA should modify its definition of "adequate warning properties." OSHA should change "hazardous chemical" to "gas or vapor" to clarify that warning properties are not a concern with particulates since, in most cases, they do not have warning properties. Also, warning properties are not

a concern with particulates since filters do not have breakthrough; rather, filtration efficiency increases with filter loading.

OSHA Should Modify Its Definition Of "Positive Pressure Respirator."

OSHA should modify its definition of "positive pressure respirator." OSHA's definition excludes powered air-purifying respirators, hoods, helmets and loose-fitting facepieces. OSHA should adopt the ANSI Z88.2 (1992) definition which includes all respiratory inlet coverings and acknowledges that positive pressure is not necessarily maintained all the time.

OSHA Should Modify Its Definition Of "Service Life."

OSHA should modify its definition of "service life." We suggest that the phrase, "this concentration is determined by the manufacturer for each type of cartridge or canister for particular substances," be deleted since employers and other people often run service life tests.

Section (d) Selection of respirators

OSHA Should Adopt Appropriate Performance Language Contained In ANSI Z88.2 (1992) On Availability Of Respirators.

OSHA should adopt appropriate performance language contained in ANSI Z88.2 (1992) on availability of respirators. We agree that appropriate respirators need to be selected, but do not agree that OSHA's proposal to require various respirators will achieve this goal. OSHA has not adequately supported the benefits that may be derived from making multiple respirators available.

First, the record does not support and OSHA has not demonstrated the conclusion that a better fitting respirator can be selected from a group of respirators. This will be discussed in greater detail in our comments on section (f) fit testing. Second, though most workplace protection factor studies used a smaller selection of respirators than OSHA would require, the results demonstrate that adequate protection was achieved.

As noted by OSHA, qualitative or quantitative fit testing can be used to select a respirator. When qualitative fit tests are used, the results are simply pass or fail; no distinction on the degree of passing can be made. When quantitative fit tests are used, numbers are obtained. However, as will be discussed in our comments on section (f) fit testing, the record demonstrates that these numbers are not perfect indicators of performance.

In the respirator studies by Lenhart[1], Dixon[2], Colton[3,4], and Gabuory[5], a single manufacturer's elastomeric respirator was available for fit testing. In each of these studies, the workplace protection factor data showed that adequate protection was achieved. In studies by Nelson[6], Gosselink[7] and Myers[8], the participants were fitted with several respirators. No significant difference in performance between types was noted.

OSHA has also not addressed the difficulty and costs involved to maintain different face sizes and manufacturers' equipment. This is particularly troublesome if OSHA were to require the selection of facepieces for self-contained breathing apparatus (SCBA). In many cases SCBAs are staged

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[1] **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).

[2] **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)

[3] **Colton, C. E. , J. O. Bidwell and H. E. Mullins**: "Workplace Protection Factors of a Half-Facepiece High Efficiency Respirator in Different Environments " Paper presented at the 1994 American Industrial Hygiene Conference, Anaheim Ca. May 1994

[4] **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).

[5] **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).

[6] **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).

[7] **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).

[8] **Myers, W**. Workplace Protection Factor Studies Report Prepared for the National Paint and Coatings Association Jnauary 1993.

throughout a process to be used in an emergency; they are not assigned to individual employees. The effect of this requirement would be that employers would need to maintain at least two sets of SCBAs. We believe that OSHA should adopt the following performance language from ANSI Z88.2 (1992) on availability of respirators:

> "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."

OSHA Should Include A Respirator Selection Process Similar To That Contained In ANSI Z88.2 (1992) In A Non-Mandatory Appendix.

OSHA should include a respirator selection process similar to that contained in ANSI Z88.2 (1992) in a non-mandatory appendix. The selection process in ANSI Z88.2 (1992) section 7 is more clear than the process proposed by OSHA. For example, OSHA does not address particle size, vapor pressure and the selection of specific filters for some exposures (paint spray filter for paint).

OSHA Should Use ANSI's Z88.2 (1992) Assigned Protection Factors.

OSHA should use ANSI's Z88.2 (1992) assigned protection factors. OSHA has proposed the use of NIOSH assigned protection factors which 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 apparent difference in performance rating, while they do in negative and pressure demand modes. The source of the air supply, bottle or airline, negative or powered flow, leads to different levels of performance according to NIOSH.

OSHA proposes the use of assigned protection factors listed in NIOSH's respirator decision logic (RDL). OSHA chose the NIOSH values rather than the more recent values listed by 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.*" OSHA has not explained why they reached this conclusion. Both groups based their assigned protection factors on workplace protection

factor (WPF) studies and laboratory studies. As a result, the numbers they arrived at should not be dissimilar unless the data base each used was significantly different.

Even though OSHA has not directly requested comments on assigned protection factors and how they are derived, the comments made by OSHA in the proposal on some of the workplace protection factor studies leads us to believe that OSHA has misinterpreted some of the data. When the record developed during the commenting and hearing process is reviewed, we believe that sufficient evidence will be provided that shows that the ANSI assigned protection factors are appropriate.

OSHA states that "*...By contrast, a published workplace protection factor study by NIOSH (Ex. 38-2) of the performance of disposable dust mist respirators provides results showing lower protection factors which cannot be ignored.*" This study should not serve as a workplace protection factor study because it has two serious deficiencies that bias the data.

First, the respirator studied had a dust/mist approval. A quantitative fit test was used to check the respirator fit. A quantitative fit test requires the use of high efficiency filters to limit filter penetration. As a result, it does not appear that an adequate quantitative fit test could be achieved since the fit factor measured would include both filter and face seal leakage.

Second, the analytical method, measurement of mass, was not precise. The contaminant in the workplace was a cement dust. The mass measured inside the facepiece included water of hydration of the cement and any other material that was exhaled from the body. As a result, the workplace protection factors measured may have been artificially biased and low.

Differences Between NIOSH And ANSI Assigned Protection Factors

OSHA has chosen to use the assigned protection factors listed by NIOSH in the RDL. In the NIOSH RDL, there is no information that specifies which data was used in reaching an assigned protection factor. There is a list of references from which we assume the data was reviewed. Since both NIOSH and ANSI based their assigned protection factors on workplace protection factor studies

and laboratory studies, the assigned protection factors they developed should not be dissimilar unless the data base each used was significantly different.

NIOSH lists single-use and quarter masks with an assigned protection factor of 5. These are listed by ANSI with half masks and given an assigned protection factor of 10. NIOSH based the assigned protection factor of 5 on the Los Alamos study[9] which determined the assigned protection factor by quantitatively fit testing the respirators with a panel of volunteers. The fit test unit was a sodium chloride system with a 0.6 µm MMAD particle. It is likely that the fit factor measured included both face seal and filter leakage since the filters were not HEPA filters. There have been no workplace protection factors studies reported on these types of respirators.

It appears that the respirators were tested without the benefit of a pretest qualitative or quantitative fit test. As a result, it appears that the data generated by Los Alamos represents the expected assigned protection factor that could be achieved without the fit testing that is required by OSHA in the proposal and by ANSI Z88.2 (1992). The fit testing required would detect the poorer fitting respirators at the same efficiency as a half mask respirator. From this, no reason appears to exist that would distinguish half masks from quarter masks.

For full facepiece respirators, NIOSH lists an assigned protection factor of 50 while ANSI lists 100. NIOSH based the assigned protection factor of 50 on the Los Alamos study. As noted by OSHA in the proposal, the author of the Los Alamos study:

> "...in his subsequent response to the ANPR, (Ex. 15-27), and in a later comment on a variance application in 1984 (Ex. 24-11), recommended that negative full facepiece respirators be assigned a protection factor of 100 provided a fit factor of 1000 could be obtained in the test booth. It was understood (although not stated in his response) that his reason for revising his recommendation was that the one respirator which performed so poorly in the original tests had been taken off the market."

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[9] **Hyatt, E. C.** Respirator Protection Factors. Informal report No. LA-6084- MS (1976) University of California, Los Alamos National Laboratory, Los Alamos NM.

There is a single workplace protection factor study by Colton[10] which reported on a full facepiece respirator in a lead environment. The data from that study supports an assigned protection factor of 100.

For powered air purifying respirators, NIOSH only lists two types, loose fitting and tight fitting. The ANSI standard lists four types, half mask, full facepiece, loose fitting facepiece and helmet/hoods. According to the RDL, the assigned protection factor is based on WPF data or laboratory data that is more recent than the Los Alamos data.

Reviewing the list of references in the RDL, there are two studies with half mask powered air-purifying respirators (PAPRs) and only one WPF study that was conducted with a full face PAPR. In the study by Myers and Peach, the authors reported that leakage of silica occurred where the breathing tube connects to the blower. As a result, this study may not predict actual performance of the half mask and full face PAPR that were in the study. Bently[11] reported on simulated WPF measurements for full and half facepiece PAPRs. The mean quantitative fit factor for two different half mask PAPRs was 14,000 and 83,000, while the full facepiece units measured 2,500 and 100,000.

From the record, it is impossible to determine the basis for NIOSH's assigned protection factors for tight fitting respirator PAPRs. With negative pressure and pressure demand supplied air respirators, NIOSH appropriately differentiated between half and full facepieces. However, we were surprised to note that the difference in negative pressure and pressure demand respirators did not carry over to PAPRs.

The NIOSH assigned protection factor for the "*loose fitting*" PAPR is the same as the assigned protection factor that ANSI assigns to "*loose fitting facepiece*" PAPRs. Reviewing the references

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[10] **Colton, C. E., H. E. Mullins and C. R. Rhoe**: "Workplace Protection Factors for a Full Facepiece Respirator". Paper presented at the 1989 American Industrial Hygiene Conference, Saint Louis Mo. (May, 1989).

[11] **Bently R. A., G. J. Bostock, D. J. Longson, and M.W Roff**: Determination of the Quantitative Fit Factors of Various Types of Respiratory Protective Equipment *J. Int. Soc. Respir. Prot. 2(4)*:313-337(1984)

listed by NIOSH, each of the studies used were conducted with the loose fitting facepiece style as defined by ANSI.

For helmet/ hood PAPRs as defined by ANSI, Keys[12] demonstrated that assigned protection factor of 1000 was appropriate for these respirators. This supports ANSI's choice to define two different types of loose fitting PAPRs, helmet/hoods and loose fitting facepieces, and correctly assigns different assigned protection factors to these types.

ANSI and NIOSH have the same assigned protection factors for continuous flow supplied air respirators as they do for PAPRs. NIOSH listing two types tight and loose fitting while ANSI lists four types. We assume that NIOSH based the assigned protection factors on the similarity in flow rates between the PAPR and the continuous flow respirators. If so, then the assigned protection factors listed by ANSI are correct.

NIOSH has an assigned protection factor of 1000 for half mask pressure demand respirators, while ANSI chose a value of 50. The ANSI value is consistent with the value for the PAPR and continuos flow respirator. CMA questions whether the addition of positive pressure could lead to that much improvement in performance. For the full face pressure demand respirator, ANSI assigns 1000, while NIOSH assigns 2000. When an escape is added to the airline respirator (making it equivalent to an SCBA) NIOSH increases the assigned protection factor by a factor of 5. We do not understand how the addition of air from a bottle rather than an air line causes an increase in performance.

CMA Supports OSHA's Assessment Of Air-Purifying Respirators, But Disagrees With The Agency's Application.

CMA supports OSHA's assessment of air-purifying respirators, but disagrees with the agency's application. We support the position that OSHA has taken recognizing that circumstances exist under which it may be safe or necessary to use air-purifying respirators despite the absence of adequate warning properties. We disagree that this should be limited to situations where the odor,

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[12] **Keys, D. R., H. P. Guy, and M. Axon**: "Workplace Protection Factors of Powered, Air-Purifying Respirators". Paper presented at the 1990 American Industrial Hygiene Conference, Orlando Florida (May, 1987)

taste, or irritation threshold is not more than three times the hazardous exposure level. CMA supports ANSI Z88.2 (1992) language for using cartridges with materials that lack adequate warning properties.

We agree with the analysis by OSHA in the proposal that:

> "...Allowing such use would require an examination of the toxicity of the chemical, its odor threshold, the health consequences of particular exposure levels, breakthrough time for the chemical for the type of respirator that will be used, how long the respirator will be used during the workshift, and the concentrations of the chemical that are found in the workplace. Calculating the service life of a particular respirator cartridge or canister for a chemical with poor warning properties would be possible using these facts and an appropriate safety factor."

The calculation would not be difficult where workplace exposure levels vary greatly throughout the day and from day to day as OSHA states. There are many statistical techniques that can be used to determine the average and percentiles of concentrations from monitoring data that would allow someone to specify a predictable use concentration for setting of a change out schedule.

For example, one could calculate the 95th percentile exposure and use that value as the maximum likely concentration. A "change schedule" could be set at 50% of the service life at the maximum likely concentration. A cartridge that lasted 8 hours at 100 ppm, could be used in setting where the estimate of the 95th percentile concentration was 50 ppm or less for a time period of 8 hours or less.

OSHA believes that "*...if the level at which the warning property exists is within three times the hazardous exposure level, OSHA believes that a sufficient margin of safety will be provided, since even a partial breakthrough is unlikely to reduce the protection factor from 10 down to three under the foregoing restrictions on use.*" We are unsure of the basis for the statement made by OSHA that for organic vapor and other cartridges the breakthrough process is such that there is not a partial breakthrough. Rather the cartridge is nearly 100% efficient until the adsorption capacity is reached, then the concentration of material that "breaks through" the cartridge rises rather rapidly.

Paragraph (d)(8)(ii) would require employers to perform testing to determine odor or irritant thresholds for a large number of chemicals that have no published odor thresholds. This might require

creating an odor testing facility and establishing a panel of trained odor testers by each employer. OSHA should not impose any requirement that mandates odor testing.

EPA's New Chemicals Exposure Limits program, like ANSI, allows the use of cartridges for materials up to ten times the exposure limit. However, ANSI does not allow the use of change out schedules for materials that have a ceiling limit.

OSHA, in the substance specific standards, does not limit the use of cartridges to three times the exposure limit for the materials such as acrylonitrile where the odor threshold is approximately ten times the PEL. OSHA has also issued a letter of interpretation which supports using air purifying respirators for substances that lack adequate warning properties. (A copy is attached to these comments.) We believe that following ANSI Z88.2 (1992) language is appropriate for using cartridge with materials that lack adequate warning properties:

> m) If the contaminant is a gas or vapor and has poor warning properties, the use of an atmosphere-supplying respirator is generally recommended. When atmosphere-supplying respirators cannot be used because of the lack of a feasible air supply or because of the need for worker mobility, air-purifying devices should be used only if:
>
> 1) the air-purifying respirator has a reliable end-of-service-life indicator that will warn the user prior to contaminant breakthrough or
>
> 2) a cartridge change schedule is implemented based on cartridge service data including desorption studies (unless cartridges are changed daily), expected concentration, pattern of use, and duration of exposure have been established, and the chemical does not have a ceiling limit.

CMA Supports Using ANSI Z88.2 (1992) Language For Selection of Most Appropriate Respirator

CMA disagrees with the Construction Advisory Committee for Occupational Safety & Health's (CACOSH) recommendation specifying the appropriate respirator as most protective. CMA supports using ANSI Z88.2 (1992) language that allows for exposures to be estimated or measured. CACOSH makes the point that construction work situations are not stable, and that monitoring results for a particular individual operation would likely not be returned in time by a laboratory before that task was completed. We believe that previous monitoring results can be used, along with past experience

with similar work operations, to estimate exposure levels. ANSI Z88.2 (1992) anticipates this type of problem and for respirator selection states that one should:

> "Measure or estimate the concentration of the contaminant(s)."

In many work situations it is relatively straightforward to make an estimate of the concentration based on the type of operation and the location of the job. For example, someone sanding a wood surface is unlikely to ever generate a sanding dust level more than ten times the exposure limit for wood dust. A half mask would be adequate respiratory protection.

CMA Supports The Inclusion of Provisions That Would Allow The Use Of Non-Approved Respirators When No NIOSH Approved Devise Is Available.

CMA supports the inclusion of provisions that would allow the use of non-approved respirators. We propose that where an employer is using a respirator where no NIOSH approved device is available that the employer be required to substantiate and document the efficacy of the equipment. As discussed above, this would entail documenting service life of cartridges used for materials that lack adequate warning properties or documenting that air supplied suits have sufficient air flow and do not allow for entry of unwanted substances under expected use conditions.

In the proposed rule, OSHA invited comment on whether and how an approval procedure could be added to the standard for respirators that are not approved. The majority of situations occur for equipment that does not fall into one of the NIOSH approval schedules, such as air-supplied suits. Some method of providing for non-approved equipment is needed in the standard.

We expect that situations that require a respirator for which there is no NIOSH approval schedules will be limited. The employer using such a device will most likely know more about the specific situation than either NIOSH or OSHA. A system requiring approval from OSHA or NIOSH for each use would be very impractical.

Section (e) Medical evaluation

CMA Supports the Adoption of Alternative Three, As Described In The Preamble, For Medical Evaluation.

CMA supports the adoption of alternative three, as described in the preamble to the proposed rule, for medical evaluation. We support the need for initial medical evaluations, followed by periodic reviews, such as the administration of questionnaires, on an age-related schedule to be determined by a physician. Medical evaluations should be conducted by a physician, or a licensed health professional under the direction of a physician. The content of the medical evaluation should be left to the judgment of the individual providing the evaluation.

CMA's support for alternative three is based on the belief that this proposed rule should only address respirator use. Responsible companies should determine that employees are fit for duty prior to assessing their qualification to wear respirators. This rule should be limited to respirator qualification, to include initial examinations, follow-up questionnaires, fit testing and training.

The Five Hour Threshold for Medical Evaluation Is Not Necessary.

The five hour threshold for medical evaluation is not necessary if OSHA selects alternative three for medical evaluation. Individuals required to wear respirators less than five hours per week should be covered by alternative three. However, CMA recommends that employees or visitors required to wear respirators for escape or pass through/walk through activities be exempted from medical evaluation. These people should be instructed on the use of these respirators, but should not need medical approval or detailed training.

OSHA Should Not Include MVV.25 As A Screening Test For Respirator Wearers

OSHA should not require MVV.25 as a screening test for respirator wearers. The test is not useful in determining an individual's potential for problems associated with wearing a respirator under normal conditions. Physicians may, however, use this test at their discretion.

OSHA Should Not Require Assessment of Tachycardia, Hearing Ability And Tympanic Membrane Defects In Respirator Evaluation.

OSHA should not require assessment of tachycardia, hearing ability and tympanic membrane defects in respirator evaluation. CMA believes that assessment of these things has little to do with achieving appropriate levels of protection from the use of respiratory protection equipment.

OSHA Should Not Include Exercise Stress Tests As A Required Part Of The Medical Evaluation For Those Required To Use SCBAS.

OSHA should not include exercise stress tests as a required part of the medical evaluation for those required to use SCBAs. While valuable to assess general fitness for duty, exercise stress tests are not useful in determining an individual's potential for problems associated with wearing a respirator under normal conditions.

OSHA Should Not Address Specific Tests In Mandatory Requirements Of Its Respiratory Protection Rule.

OSHA should not address specific tests in mandatory requirements of its respiratory protection rule. Guidance should be included in a non-mandatory appendix. OSHA should include the following contents of an initial medical evaluation in a non-mandatory appendix: focused medical exam, focused physical exam, laboratory testing to include pulmonary function, EKG, and other tests deemed necessary by the individual conducting the evaluation. OSHA should include the following contents of a follow-up questionnaire in a non-mandatory appendix: history of respirator use, history of problems associated with respirator use, history of other symptoms or conditions (shortness of breath, coughing or wheezing, chest pain, claustrophobia, hearing, lung or nervous system disorders), smoking history and any other health concerns.

OSHA Should Not Mandate An Annual Review of Medical Status.

OSHA should not mandate an annual review of medical status. As discussed earlier, the medical status of employees should be reviewed on an age-related schedule, or on a more frequent

basis if necessary. ANSI Z88.6 and NIOSH RDL are guidelines that may be used at the discretion of the evaluator.

OSHA Should Allow Other Health Professionals to Perform Medical Evaluations and Administer Questionnaires.

OSHA should allow other health professionals to perform medical evaluations and administer questionnaires. This could include occupational health nurses, nurse practitioners and physicians assistants performing under the direction of licensed physicians.

OSHA Should Require Medical Exams For All SCBA Wearers.

OSHA should require medical exams for all SCBA wearers, due to the stress of wearing them. The content of the exam would depend on the job and be left to the discretion of the examining health professional.

Section (f) Fit testing

OSHA Should Reconsider Its Validation Criteria For Alternative Fit Test Protocols.

OSHA should reconsider the validation criteria it has selected for alternative fit test protocols. It should do so because: (1) OSHA's level of confidence is more stringent than the currently accepted qualitative fit tests (QLFT), (2) OSHA has not clearly explained why it believes a higher standard is justified, and (3) the measurement bias is too great to support such a high confidence level.

OSHA is proposing to allow the use of QLFT or quantitative fit tests (QNFT), where they are validated, to provide equivalent or better reliability than the protocols in OSHA's mandatory appendix. Both the qualitative and quantitative validation criteria for new fit test methods require that the fit test data submitted for approval demonstrate statistically that the fit test method be as protective as currently approved QNFT. OSHA defines this as requiring the test to identify 95% of users with fit factors less than ten times the assigned protection factor at a 95% confidence level. Because OSHA has not defined the statistical test to be used, we shall assume that the test uses binomial theory.

CMA does not believe it is appropriate to judge alternative fit tests using OSHA's proposed statistical methods. First, OSHA has noted that the existing qualitative fit test methods do not meet OSHA's proposed performance levels. From the record, it is unclear why OSHA believes the acceptance criteria should be more stringent for the new protocols. Second, the level of confidence OSHA has selected results in a much stricter standard than the performance of the oil mist quantitative fit test. The quantitative system has a measurement bias of at least 17%,[13, 14] and includes a measurement error of about 65%[15] for particles with a diameter of 1 μm due to lung losses. As a result it may be inappropriate to require such a high degree of statistical certainty when compared to the sensitivity of the test's measurement system.

CMA recommends that OSHA require that qualitative fit tests detect at least 95% of people with fit factors less than 10 times the assigned protection factor for the type of respirator it is designed to evaluate. We also suggest that a range of poor fitting respirators be used in the evaluation, including those with fit factors both above and below the specified criteria. We also proposes that a 90% confidence interval be provided, so that an employer can estimate the reliability of the data supporting the fit test method.

OSHA Has Not Adequately Explained The Need To Fit-Test All Tight-Fitting Respirators.

OSHA has not adequately explained the need to fit-test all tight-fitting respirators. Relevant research does not support OSHA's conclusion that all tight-fitting respirators need to be fit tested. However, we agree that negative pressure respirators should be fit tested.

In section (f)(3), OSHA requires that all tight-fitting air purifying and all tight-fitting atmosphere supplying respirators be either quantitatively or qualitatively fit-tested. In section(f)(6)(iii), OSHA specifically requires that tight-fitting air purifying respirators and tight-fitting atmosphere

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[13] **Myers, W.R., J.R. Allender, W. Iskander, and C. Stanley:** Causes of In-Facepiece Sampling Bias--1. Half-Facepiece Respirators. *Ann. Occup. Hyg.* 32(3):345-359 (1988).

[14] **Myers, W.R. and J.R. Allender**: Causes of In-Facepiece Sampling Bias--11. Full-Facepiece Respirators. *Ann. Occup. Hyg. 32(3):361*372 (1988).

[15] **daRoza, R. A.**: Minimizing the Effect of Lung Loss on Measured Respirator Fit Factors. Lawrence Livermore National Laboratory, Livermore, California.

supplying respirators be qualitatively or quantitatively fit tested. OSHA's proposal specifies testing of only the mask, and not the entire respirator unit. OSHA appears to have based these requirements on comments it received suggesting: (1) that positive pressure respirators do not always maintain positive pressure, (2) that this may result in possible adverse effects, and (3) that this may require quantitative fit-testing.

In Exhibit (36-26), one commenter notes that, in the laboratory, he has monitored negative pressure spikes during fit factor measurements with SCBA's. However, OSHA has not provided an adequate analysis of the possible effect these occurrences may have on employee protection. OSHA has not clearly shown that a momentary negative pressure spike is likely to lead to a significant reduction in protection. Campbell et. al.[16] provide information on the likelihood of negative pressure spikes occurring during the wearing of an SCBA. Only 4 times out of 57 did any negative pressure excursions occur. They calculated the possible protection factor and concluded it could be two orders of magnitude higher than the assigned protection factor of 10,000. Bently[17] et. al. measured pressure and fit factors for people wearing SCBAs. They recorded 173 instances of negative pressure during 400 time periods. However the fit factors they measured were all greater than 54,000. This data would lead us to believe that although negative pressure can occur inside the facepiece of pressure-demand SCBAs, it is unlikely that the length of excursion is great enough to significantly affect employee protection. This effect is likely to be even less for the pressure-demand air line respirators that have an ANSI assigned protection factor of 1000 (and a proposed 2000 by OSHA).

Where A Respirator Fails An Initial Fit Check, OSHA Should Clearly Allow Respirator Fit Adjustments To Be Made.

Where a respirator fails an initial fit check, OSHA should clearly allow respirator fit adjustments to be made. In the procedure for fit testing, OSHA states that another facepiece shall be selected and retested if the test subject fails the fit check tests. If a respirator is improperly adjusted it may fail a fit check. Where this occurs, OSHA should clearly allow for adjustments to be made to the

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[16] **Campbell D. L., G. P. Noonan, T, R. Merinar and T. A. Stobbe**: Estimated Workplace Protection Factors for Positive Pressure Self-Contained Breathing Apparatus *Am. Ind . Hyg. Assoc. J* 55(4): 322-329 (1994)

[17] **Bently R. A., G. J. Bostock, D. J. Longson, and M.W Roff**: Determination of the Quantitative Fit Factors of Various Types of Respiratory Protective Equipment *J. Int. Soc. Respir. Prot. 2(4)*:313-337(1984)

respirator, and OSHA should allow it to be rechecked. In many cases, a simple adjustment allows the person being fit tested to change the fit of the respirator and pass a fit check. Appendix A should allow for adjustment of the fit before a respirator is rejected outright as poor fitting.

CMA Agrees With OSHA That Isoamyl Acetate and Saccharin Are Appropriate Fit Test Agents, But CMA Does Not Support Using The Irritant Smoke Test.

CMA agrees with OSHA that the isoamyl acetate and saccharin fit tests have been shown to be effective. However, we do not support using the irritant smoke test. Unlike the saccharin and isoamyl acetate fit tests, the concentrations generated during the test protocol required by OSHA for the irritant fume fit test have not been adequately measured and shown to be reproducible.

In qualitative fit testing no direct measurements of the test and response concentrations are made. The saccharin and isoamyl protocols adopted by OSHA in its lead standard have very specific instructions for determining the response of a person to the test material and the generation of the test atmosphere. For the isoamyl acetate test, Nelson et. al.[18] demonstrated that a carefully measured solution of water and isoamyl acetate produced a 1 ppm concentration of isoamyl acetate in the head space of a jar. This formed the basis for an odor response test in their isoamyl acetate QLFT. They also demonstrated that a known reproducible atmosphere of approximately 150 ppm could be produced in a test enclosure with 1 ml. of isoamyl acetate. This concentration was validated for exercise times of 30 seconds for a six exercise routine.

Theoretically, this test protocol would fail people with fit factors less than 150. Nelson et. al. validated their test protocol by performing a QLFT and QNFT fit test on a number of subjects. Two out of 92 people who had measured fit factors less than 100 passed the test, while 90 failed the isoamyl acetate fit test. The two that passed the test with fit factors less than 100 had factors greater than 90. The best estimate that the "DuPont" protocol would detect a fit factor less than 100 is 98%. The 90% confidence interval is 93 to 99.5%. In other words, this provides a 90% confidence that the isoamyl

[18] **Nelson T. J., O. T. Skredtvedt, J. L. Loschiavo and S. W. Dixon** "Development of an Improved Qualitative Fit Test Using Isoamyl Acetate", Journal of the International Society for Respiratory Protection 2(2): 225-248 (1984)

acetate protocol would detect at least 93% of the fit factors less than 100, but could do as well as detecting 99.5%.

For the saccharin fit test, one CMA member company, 3M, developed a test protocol using a saccharin mist. A person's head was placed in a small test hood and their ability to taste a weak concentration of a saccharin solution was evaluated. Next while wearing the respirator to be tested, they were exposed to a solution of saccharin that is 100 times stronger that the taste solution. As a result, the saccharin test should have a theoretical passing fit factor of 100.

Marsh evaluated the 3M saccharin test protocol by comparing the results of the saccharin QLFT with a QNFT[19]. He found that 4 out of 121 passed the saccharin fit test with fit factors below 100, while 117 people failed. Marsh also found that temperature and humidity had a slight effect on the size distribution of the aerosol. Marsh would estimate that 97% of fit factors less than 100 would be detected, with a 90% confidence interval of 92.5 to 99.5%.

The amount and quality of available data is one factor in the confidence interval estimate of whether a test will fail. With more data the range for the confidence interval decreases. Combining other studies done with the saccharin protocol with the Marsh data, would indicate that the saccharin test should detect 96% of the fit factors less than 100, with 90% confidence limits of 93 to 98%

Marsh also evaluated an irritant fume protocol[20]. The test protocol was similar to that evaluated by Hardis et. al.[21] First test subject was exposed to a slight concentration of the irritant fume to determine if they were irritated by that tube. Next, while wearing the respirator and seated in front of a hood, they were exposed to a concentration of the fume from approximately 1 meter. The distance was decreased until the end of the glass tube was approximately 6 inches from the sealing surface of the respirator. Marsh found that 4 of 108 people with fit factors less than 100 passed the

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[19] **Marsh J. L.**, Evaluation of Saccharin Qualitative Fitting Test For Respirators *Am. Ind . Hyg. Assoc. J.* 45(6): 371-376 (1984)

[20] **Marsh J. L.**, Evaluation of Irritant Smoke Qualitative Fitting Test For Respirators *Am. Ind . Hyg. Assoc. J* 45(4): 245-249 (1984)

[21] **K. E. Hardis, C. A. Cadena, G. J. Carlson, R. A. daRoza and B. J. Held**; Correlation of Qualitative and Quantitative Results From Testing Respirator Fit, *Am. Ind . Hyg. Assoc. J.* 44(2): 78-87(1983).

irritant fume protocol while 104 failed the test. Hardis used ten (10) as an indicator of an adequate fit factor for the QNFT and found that all people with fit factors greater than (ten) 10 passed their test.

The test protocol used by Marsh and Hardis differed from the one required by OSHA in its 1978 lead in industry standard. OSHA requires that, during the testing phase, a low flow pump delivering 200 ml/min air be used to produce the irritating fume. OSHA, Marsh, and Hardis did not produce any data on the concentrations generated during the testing or sensing check phase of the test.

Dixon and Skredtvedt reported on the concentration of stannic chloride fume that produced a 50% decrease in the respiratory rate (RD_{50}).[22] They reported that concentrations 1/10th of the RD_{50} are believed to correlate with irritating concentrations in humans. The RD_{50} for stannic chloride is 6400 mg/m^3, the threshold of response was 700 mg/m^3. During simulated fit tests, they reported that the concentration of stannic chloride was 2500 mg/m^3. NIOSH measured the concentration of hydrogen chloride during fitting tests[23], including the concentration of hydrogen chloride with a hood, and without, on days of low (14% RH) and high (53%RH) humidity. In the low humidity without a hood, the concentration ranged from <1 ppm at a distance of 24 inches to 2,700 ppm at 2 inches. In high humidity the concentration ranged from 100 ppm at 6 inches to 11,900 ppm at 2 inches.

Unlike the saccharin and isoamyl acetate fit tests, the concentrations generated during the irritant fume fit test protocol required by OSHA have not been adequately measured and shown to be reproducible. Theoretically, the irritant smoke fit test should be able to detect fit factors of from 4 to 35 based on the stannic chloride measurements and an irritation threshold of 70 to 640 mg/m^3 based on the measurements made by Dixon.

Finally, it is unclear whether the irritant smoke test agent will satisfy OSHA's own requirements: (1) that the test agent be relatively non-toxic, (2) that concentrations during test do not exceed the PEL, and (3) that the test does not create a hazard to the operator. From the data generated

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[22] **Dixon S. W. and O. T. Skretvedt**: "Relative Hazards and Safe Use Precautions for Qualitative Respirator Fit Test Atmospheres", Paper presented at the 1981 American Industrial Hygiene Conference, Portland Oregon. May 1981.

[23] Health Hazard Evaluation Report HETA 93-040-2315, Anchorage Fire Department, Anchorage Alaska. U. S. Department of Health and Human Services, Public Health Service Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, May 1993.

by NIOSH on the concentration of hydrogen chloride during an irritant smoke test, the smoke tube produces concentrations of hydrogen chloride that exceed not only its ceiling limit (5 ppm), but also its IDLH value (100 ppm) and toxic end point level (309 ppm). Thus by OSHA's own proposed criteria for a qualitative fit test, irritant smoke appears inappropriate.

OSHA Should Reconsider The Value And Appropriateness Of Specific Fit Test Exercises.

CMA supports the use of the standard fit test exercises, but does not believe OSHA has adequately explained the value of the grimace exercise, the bending over exercise, or jogging. OSHA should reconsider the value and appropriateness of these specific fit test exercises. First, for saccharin and isoamyl acetate tests, CMA believes that the grimace exercise may not be appropriate. Second, CMA is unsure whether the bending over exercise, or its substitute -- the jogging exercise, will provide any necessary or appropriate data for the use of respirators. Finally, OSHA has not adequately explained the benefits it perceives from expanding the exercise interval from 30 seconds to one minute.

OSHA is proposing test exercises consisting of (1) normal breathing, (2) deep breathing, (3) turning head side to side, (4) moving head up and down, (5) talking out loud, (6) grimacing, (7) bending over or jogging in place if the test unit is not large enough for the test subject to bend at the waist, and (8) normal breathing. The exercises are to be done for one minute, except the grimace is to be done for 15 seconds. CMA does not support the inclusion of the grimace or the bending over exercises in the test exercise series. The grimace exercise has been added to check whether a respirator fit will return to an acceptable level after the seal is broken. For qualitative fit tests, breaking the seal momentarily will eliminate the person's ability to detect leakage. The person may not be able to determine if the respirator reseals.

OSHA has not adequately explained the benefits to be derived by adding the bending over exercise -- or its substitute, the jogging exercise -- to the regimen. Most workplace protection factor studies have utilized the traditional exercises, excluding grimacing, bending over, and jogging. OSHA has not provided adequate research or data that would suggest that added exercises would measurably improve actual respirator protection. In addition, jogging and bending over are most likely not very

good substitutes for each other. The bending over exercise is a low impact exercise, while jogging causes a higher vertical movement rate to the mask.

Finally, OSHA has not adequately explained the benefits it perceives from expanding the exercise interval from 30 seconds to one minute. OSHA provides no data that an exercise period of one minute provides any benefit over a test period of 30 seconds. However, Marsh did examine the need for a 30 second or minute test. He concluded:

> There has been a considerable amount of disagreement as to the length of time that test exercises should be performed during a fitting test. The 30-second period per exercise was selected based on the experience gained in the conducting of thousands of quantitative fit tests on employees at Los Alamos National Laboratory. It was felt that there would be no significant difference in the fit factor obtained using 30 seconds per exercise or some longer period of time. In order to document this belief, 25 strip chart recordings from previous quantitative tests, using 1-minute test exercises, were analyzed. These tests had been run on an anthropometric panel wearing full facepiece negative-pressure respirators. The FFs were calculated using both the 1-minute test exercises and the first 30 seconds of each test exercise. The % difference in the calculated FF was then determined. For the 25 tests the average % difference was found to be 2.4% with a standard deviation of 4.1%.[24]

In addition, the studies done validating the isoamyl acetate and saccharin fit tests used 30 second exercise periods. As a result, these is significant evidence that a 30 second exercise period may be sufficient to determine whether a respirator fits adequately.

OSHA Should Include The TSI Portacount Fit Test Method As Protocol For Quantitative Fit Testing.

Sufficient evidence has been gathered to enable OSHA to include the TSI Portacount fit testing method as an established quantitative fit test protocol. Existing laboratory data, workplace protection factor data, and comparison studies support the Portacount as a viable method of fit testing. daRoza [25] concluded that the Portacount showed a good correlation with a photometer during simultaneous measurements of fit factors. The fit factor measurements were biased, with the Portacount fit factors 1.7 times less than the photometer. He also concluded that "....The Portacount could be used with

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

[25] **da Roza, R. A., A. H. Biermann, K. L. Foote, C. McCormack and C. R: Sackett**: Evaluation of Portacount for Determining Respirator Fit Factors, Part III: Human Subject Tests and Comparison with an Aerosol Photometer. Journal of the International Society for Respiratory Protection 9(3): 22-37 (1991).

ambient aerosols to confidently measure fit factors of 100. When used to measure fit factors of 1000 with ambient aerosols, several complications can occur that cause the fit factor to be low ... Although this is undesirable, it errs on the side of safety."[26]

In a number of workplace protection factor studies, [27, 28, 29] which include both full face and half mask respirators, the Portacount was used to select respirators as part of the fit test program. In each case the workplace protection factors measured were consistent with the assigned protection factor for the respirator type. This helps to demonstrate that the Portacount can distinguish acceptable respirators for use in both laboratory and workplace settings.

OSHA Should Clarify Placement Of The Sampling Probe For Quantitative Fit-Testing.

In the quantitative fit testing protocol, OSHA fails to identify where the probe for quantitative fit testing is to be located. As shown by Myers[30,31,32] improper placement of the sampling probe can lead to potential errors in the measurement of a fit factor. Even with an ideal sampling location, Myers estimated a sample bias of 17%. OSHA should specify that the sampling probe for quantitative fit testing be placed at a point approximately midway between the nose and the mouth and extend into the face-piece cavity at least one quarter of an inch.

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[26] **da Roza, R. A, et. al.**

[27] **Colton, C. E., H. E. Mullins and C. R. Rhoe**: "Workplace Protection Factors for a Full Facepiece Respirator". Paper presented at the 1989 American Industrial Hygiene Conference, Saint Louis Mo. (May, 1989).

[28] **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).

[29] **Myers, W.** Workplace Protection Factor Studies Report Prepared for the National Paint and Coatings Association January 1993.

[30] **Myers, W.R., J. Allender, R. Plummer, and T. Stobbe:** Parameters that Bias the Measurement of Airborne Concentrations within a Respirator. *Am. Ind. Hyg. Assoc. J.* 47(2):106-114 (1986).

[31] **Myers, W.R., J.R. Allender, W. Iskander, and C. Stanley:** Causes of In-Facepiece Sampling Bias--1. Half-Facepiece Respirators. *Ann. Occup. Hyg.* 32(3):345-359 (1988).

[32] **Myers, W.R. and J.R. Allender**: Causes of In-Facepiece Sampling Bias--11. Full-Facepiece Respirators. *Ann. Occup. Hyg. 32(3):361*372 (1988).

OSHA Has Not Identified The Need For Three Quantitative Fit Tests.

OSHA has not adequately explained why it believes that three fit tests are necessary for quantitative fit testing. The proposed rule requires that three tests be performed, and that the lowest fit factor determines whether the minimum required fit factor is exceeded. In addition, the results of all three tests must be above the minimum fit factor needed for that class of tight fitting air-purifying respirator. CMA disagrees that three fit tests are needed for quantitative fit testing. Workplace protection factor studies, which used quantitative fit testing as the means of qualification, all used a single quantitative fit test. The results of the studies have shown for half masks and full facepiece respirators that the assigned protection factor was achieved. A single test should be adequate to qualify a respirator for use. In addition the studies that used one qualitative fit test to qualify respirators also showed acceptable levels of performance (isoamyl acetate and saccharin tests only).

Section (g) Use of respirators

OSHA Should Clarify The Employer's Obligations In Ensuring Proper Respiratory Protection For Employees With Facial Hair.

CMA supports OSHA in recognizing that facial hair poses a problem for respirator use. However, CMA recommends that OSHA carefully craft an employer's obligations to ensure respiratory protection for bearded employees. We suggest that OSHA modify Section (g)(3) as follows:

> A respirator, either positive or negative pressure, equipped with a facepiece (tight or loose fitting) shall not be worn if facial hair comes between the sealing surface of the facepiece and the face or if facial hair interferes with valve function.

CMA Supports OSHA's Decision To Allow The Use Of Contact Lenses.

We support OSHA's proposal not to restrict the use of contact lenses. There has been no data presented to show that the use of contact lenses poses a significant hazard. In fact, it is plausible that substantial benefits could be achieved with full-face air-supplied equipment even when using glasses.

IV. COMMENTS ON PROPOSED REVISIONS TO SUBSTANCE SPECIFIC STANDARDS

CMA Recommends That OSHA Ensure Consistency Between This Standard And Respiratory Protection Provisions In Its Substance Specific Standards.

OSHA has adopted various approaches to deal with respirator provisions in substance specific standards that differ from the provisions, including those for respirator selection, that are included in this proposal. OSHA has stated its belief that in order to maintain an effective respirator program regardless of the contaminant or workplace conditions, there should be a minimum established program. Thus, for provisions in substance specific standards that are more protective than this standard, OSHA does not propose any changes.

CMA recommends that OSHA ensure consistency between this standard and respiratory protection provisions in its substance specific standards. CMA supports OSHA's desire to ensure that there are minimum respiratory protection provisions in place. CMA recommends that OSHA carefully review the substance-specific rulemaking dockets, and review practices that are in place for meeting those requirements. Where possible, OSHA should strive to ensure consistency and minimize the potential for confusion between the respiratory protection provisions. Generally, OSHA should only include respiratory protection provisions in the substance specific standards where it has demonstrated that in dealing with the particular substance, special or unique conditions have arisen that warrant different treatment or supplemental requirements.

OSHA Should Reconcile Provisions In Substance Specific Standards Based On Data Relevant To The Individually Regulated Substances.

OSHA should reconcile provisions in the substance specific standards based on data relevant to the individually regulated substances. OSHA should include respiratory protection provisions in the substance specific standards only where it can demonstrate that unique conditions warrant them. Some examples are described in greater detail below.

In the acrylonitrile and arsenic standards, OSHA is maintaining a provision that quantitative fit testing be done when there are a certain minimum number of employees. OSHA has not adequately

described what data supports a need for these different fit testing requirements. Similarly, OSHA is requiring semi-annual fit testing in some substance specific standards. Again OSHA has not provided any data in the record supporting this difference.

OSHA is proposing that fit testing be performed before an employee first starts wearing a respirator in the work environment and at least annually thereafter, but will retain semi-annual fit testing in some substance specific standards such as acrylonitrile. In keeping the six month testing in these standards, OSHA has not been consistent. Moreover, OSHA has not demonstrated that more frequent testing gives any benefit.

Finally, OSHA also proposes to reinstate the required use of high efficiency filters for all air purifying respirators used with lead. CMA agrees that HEPA filters may be necessary for some air purifying respirators since , in some instances, filter leakage through dust/mist, and dust/fume/mist filters may pose a concern. As recognized by ANSI Z88.2 (1992), the assigned protection factor for some respirators, e.g. a full face PAPR, varies by the type of filter. However we do not agree that HEPA filters are necessary for each use of a half mask respirator with toxic substances, because we disagree with NIOSH's certification requirement to use HEPA filters for materials with exposure limits less than 0.05 mg/m3.

Filter efficiency for particulates is a function of a number of variables. The efficiency of a filter is dependent on the characteristics of the challenge aerosol as well as the filter characteristics. Characteristics such as particle size, composition, density, shape, electrical charge and flowrate are relevant in determining the filter's efficiency. OSHA has not demonstrated that an increase in filter efficiency for half mask respirators will result in an increase in performance. Respirator performance is a function of filter leakage, faceseal leakage and leakage through defects. Decreasing filter leakage will not likely have a significant effect on the other sources of leakage. Nelson[33] has shown that there are some differences between the performance of various half mask respirators equipped with the different types of filters. The mean workplace protection factor measured with a HEPA filter was significantly higher than either the mean workplace protection factor measured for dust/mist or dust/fume/mist

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[33] **Nelson T. J.**: The Assigned Protection Factor of Ten for Half Mask Respirators Amer. Indus. Hyg. J. (In press)

filters. However the best estimate of the 5th percentiles were not that different. As a result, we support the ANSI Z88.2 (1992) respirator selection criteria that requires the selection of HEPA filters based on particle size.

V. CONCLUSION

In conclusion, CMA supports OSHA's efforts to improve its respiratory protection standard, with the inclusion of these recommended changes.

Attachment I

JUN 4, 1990

MEMORANDUM FOR: REGIONAL ADMINISTRATORS

ATTN: ARA'S FOR TECHNICAL SUPPORT

THRU: LEO CAREY
Director
Office of Field Program

FROM: THOMAS J. SHEPICH
Director
Directorate of Technical Support

SUBJECT: Use of Chemical Cartridge Respirators

On February 26, the National Institute for Occupational Safety and Health (NIOSH) distributed a "Respirator Information Notice on Chemical Cartridge Respirators" which stated that since OSHA has revised the permissible exposure limits (PEL) for toxic air contaminants listed in Table Z of 1910.1000, NIOSH has decided to eliminate the maximum use concentrations (MUC) labeling requirement for all approved chemical cartridges under the provision of 30 CFR 11.150 (copies attached).

The NIOSH notice has also eliminated the labeling requirements on cartridges for protection against the exposure to organic vapors. We have received numerous inquiries concerning this issue. Since OSHA does not have specific standards for the majority of organic compounds listed in Table Z of 1910.1000, the elimination of the MUC may cause overexposure because many of these contaminants have inadequate odor warning properties. In order to ensure that the organic vapor cartridges are used properly, the attached guidelines should answer most questions when you receive inquiries concerning this issue.

Attachment

GUIDELINES ON THE USE OF CHEMICAL CARTRIDGES FOR PROTECTION AGAINST ORGANIC VAPOR EXPOSURE

1. Use Limitation:

Use of the cartridges is limited to the lowest of the three air contaminant concentrations determined by the following:

a. Immediately dangerous to life or health (IDLH) concentration.

b. 1,000 parts per million (ppm).

c. The maximum use limit (MUL) which is 10 times the OSHA permissible exposure limit (PEL).

2. These organic vapor cartridges are approved for respiratory protection against organic vapors with definite odor warning properties, meaning that the air contaminant must have a distinctive odor at concentrations at or below the permissible exposure limit established by OSHA for the air contaminant, and the odor warning properties are not affected by olfactory fatigue.

3. The use of chemical cartridges for protection against an air contaminant without definite odor warning properties is acceptable only when the use is permitted in specific OSHA health standards (such as acrylonitrile), when the cartridge has an approved end-of-service-life indicator (such as mercury), or when the cartridge breakthrough time is available based on the following test conditions:

a. Challenge concentration: 10 times the PEL.

b. Air Flow: 32 liters per minute continuously.

c. Relative humidity: 85 to 90%.

d. Temperature: 20 to 25 degree Celsius.

The breakthrough time should be calculated as the mean of at least three samples at a 95% confidence level. Unless the cartridge desorption information indicates that there is no significant desorption from overnight storage, the cartridge should be replaced at the beginning of each shift or prior to the experimental breakthrough time, whichever comes first.