THE ASSIGNED PROTECTION FACTOR OF 10 FOR HALF-MASK RESPIRATORS

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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 respirators equipped with dust/mist and dust/fume/mist filters.

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 American National Standards Institute (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 to allow these questions to be answered. The WPF studies contain few data points because these studies are difficult to perform and 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 that 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 2 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.

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TABLE I. Summary of the Studies

Study	Respirator Type	Filter Type	Fit Test	Analyte	Analytical Method	Detection Limit	Liu Probe	# People	Particle Size (Mean)
Dixon Gaboury[A]	elastomeric	HEPA	isoamyl	lead	PIXE	2 ng sample	no	11	1.8 µm
	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[A]	disposable elastomeric	DM, DFM, HEPA	saccharin	asbestos	fiber count	0.0006 fibers/mL	yes	17	0.49 µm
Gosselink[A]	disposable elastomeric	DM, DFM HEPA	saccharin	asbestos	fiber count	0.001 fibers/mL	yes	12	—
Johnston[A]	disposable	DM	saccharin	Ti, Al, Si	PIXE	9–35 ng per sample	yes	5	—
Colton—brass[A]	disposable	HEPA	saccharin	Pb, Zn	PIXE	<10 ng per sample	yes	17	dust and fume both present
Colton—Al[A]	disposable	DM	saccharin	Al	PIXE	<10 ng per sample	yes	5	~10 µm
Galvin	elastomeric	Charcoal cartridge	irritant smoke	styrene	GC	1 µg/sample	no	13	—
Myers—foundries[A]	elastomeric disposable	DFM	saccharin, quantitative (min 100 FF)	Zn, Pb	PIXE	<10 ng per sample	yes	25	dust and fume both present
—aircraft[A]	elastomeric	HEPA	quantitative (min FF 100)	Ti, Cr	PIXE	<10 ng per sample	yes	22	—
—steel mill[A]	elastomeric disposable	DM	saccharin	Fe	PIXE, AA	<10 ng per sample	yes	17	dust and fume both present
Colton—welding[A]	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_i no C_o	—	~60% > 10 µm

[A] Studies that have not been published

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 µg/m³. To qualify for the study, each subject 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 µg 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, subjects passed a saccharin qualitative fit test. Seventeen people participated in the study. Samples were collected for 30 minutes to 2 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 L 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, and 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 L/min, 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. 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 also were 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 1-hour periods for each of the 13 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] that 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 or 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, and 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, 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

For the data from several studies to be combined, 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 that are generally described but cannot be evaluated objectively. Methods of fit testing and sample collection and analysis can be evaluated objectively.

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 wearer's 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 was 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 taste or odor sensitivity and 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 also would 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 10 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 10 times the assigned protection factor times 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 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 biased the observed WPFs, 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 caused the outside samples to underestimate the concentration of manganese. As shown by Liu, a similarly 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 was 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 based on one listed in the Occupational Safety and Health Administration 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 μg/m^3, with a detection limit of 2 μg/m^3; the lowest ratio was 46 (based on a sample time of 8 hours at 2 L/min with a detection limit reported at 2 μg/m^3). Fit testing was

TABLE II. Summary of Study Parameters

Study	N	GM	GSD	5th Percentile	95th Percentile	Reason Not Included
Studies included in the analysis						
Dixon	42	3360	4.8	254	44 400	
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						
Reed	19	18	3.17	2.7	120	nonspecific 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

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 WPFs 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 1-hour sample time and the detection limit; the lowest concentration that could be measured was approximately 0.1 μg/m³).[5] Fit testing was done using the isoamyl acetate fit test. The in-mask samples were collected without the probe designed by Liu,[28] which 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 were of the size range where 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 not to have adversely affected 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, samples were analyzed for zinc, titanium, magnesium, and iron during welding.[13] For zinc the inside concentration ranged from 0.1 to 9.7 μg/m³. For outside-the-respirator samples, concentrations were from 4.2 to 1062 μg/m³. With a detection limit of approximately 15 ng/filter (or approximately 0.05 μg/m³), 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 μg/m³. The detection limit was approximately 0.08 μg/m³ for a 2-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 WPFs. 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

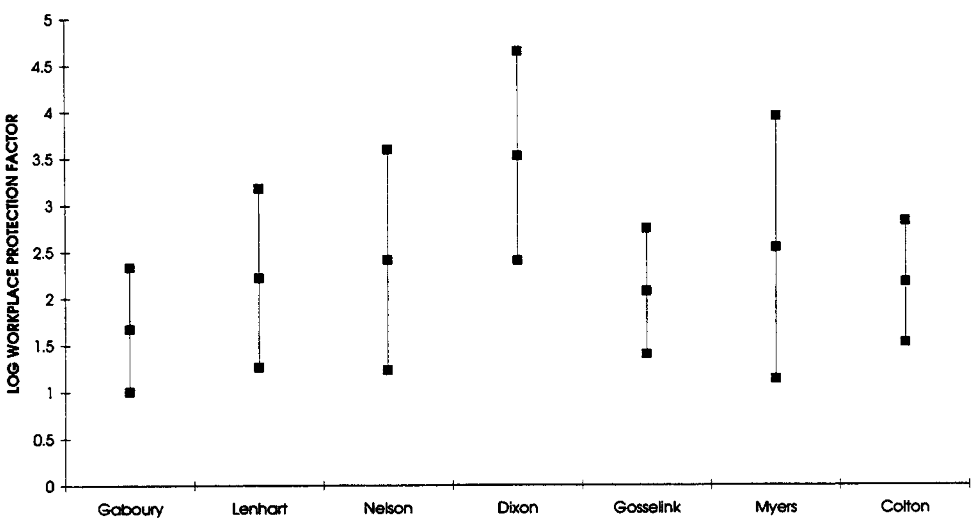

FIGURE 1. Range of 5th percentile, geometric mean, 95th percentile

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 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 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. Tables 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.

estimates of the 5th and 95th percentiles 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, 6 WPF values (or 1.5% of samples) were less than 10. 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 a 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 (Table III) 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

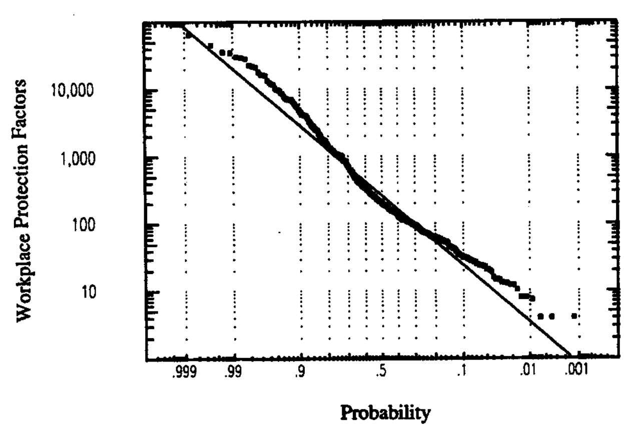

FIGURE 2. Probability plot of combined data set

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

TABLE III. WPF Data for Filter Type

	Dust-Mist		*Fume*		*HEPA*	
Study	*Number*	*GM*	*Number*	*GM*	*Number*	*GM*
Gaboury	4	48	14	46	—	—
Lenhart	—	—	—	—	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[A]

	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			

[A] 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

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 assumed to be similar. Many factors can affect the data collected during a WPF study, and several of these factors cannot be evaluated objectively, such as the lèvel 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 was significantly higher than that for respirators equipped with either DM or DFM filters, and the respirators 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.

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

When the differing styles of respirators were examined, the disposable respirators had a mean WPF that was not significantly different from that for the elastomeric respirators equipped with either DM filters or 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 DM, DFM, and HEPA filters when comparing the 5th percentiles was not that different and was 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.

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REFERENCES

1. **Nelson, T.J. and S.W. Dixon:** Respirator protection factors for asbestos, parts I and II. Paper presented at the American Industrial Hygiene Conference, Las Vegas, NV, May 23, 1985.
2. **American National Standards Institute (ANSI):** *ANSI Z 88.2 (1992), American National Standard for Respiratory Protection.* New York: ANSI, 1992.
3. **Fleiss, J.L. and A.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. 44(2)*:127–139 (1991).
4. **Johnston A.R., W.R. Myers, C.E. Colton, J.S. Birkner, et al.:** Review of respirator performance testing in the workplace. Issues and concerns. *Am. Ind. Hyg. Assoc. J. 53*: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, TX, May, 1986.
10. **Johnston, A.R. and H.E. Mullins:** Workplace protection factor study for airborne metal dusts. Paper presented at the 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 American Industrial Hygiene Conference, Orlando, FL, May, 1990.
12. **Colton, C.E., A.R. Johnston, H.E. Mullins, C.R. Rhoe, et al.:** Respirator workplace protection factor study on a half-mask dust/mist respirator. Poster presented at the American Industrial Hygiene Conferednce, Orlando, FL, May 1990.
13. **Colton, C.E. and H.E. Mullins:** Workplace protection factors for a half-mask dust/mist/fume respirator. Poster presented at the American Industrial Hygiene Conference, Salt Lake City, UT, 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. **Myers, W.:** "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*:576–583 (1993).
17. **Pally, B., J. Gample, L. Jerman, J. Allender, et al.:** 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, FL, May 1990.
18. **Revoir, W.H.:** Respirators for protection against cotton dust. *Am. Ind. Hyg. Assoc. J. 35*: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*:453–458 (1976).
20. **Smith T.J., W.C. Ferrell, M.O. Varner, and R.D. Putnam:** Inhalation exposure of cadmium worker effects of respirator use. *Am. Ind. Hyg. Assoc. J. 41*: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.] *Am. Ind. Hyg. Assoc. J. 46*:B-22–B-24 (1985).
23. "Occupational Safety and Health Standards," 29 CFR 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*: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)*:225–8 (1984).
26. **Myers, W.A., Z. Zhuang, T. Nelson, S. Sides, et al.:** 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, et al.:** Mask aerosol sampling for powered air purifying respirators. *Am. Ind. Hyg. Assoc. J. 45*:278–283 (1984).
28. *LOGAN, Workplace Exposure Evaluation System.* [Computer Software.] American Industrial Hygiene Association, 1990.
29. **Dowdy, S. and S. Wearden:** *Statistics for Reseacrch.* 2nd. ed. New York: John Wiley & Sons, 1991. pp. 321–323.