

## Field Performance Measurements of Half-Facepiece Respirators: Developing Probability Estimates to Evaluate the Adequacy of an APF of 10

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# Field Performance Measurements of Half-Facepiece Respirators: Developing Probability Estimates to Evaluate the Adequacy of an APF of 10

To evaluate the protection provided by negative-pressure, half-facepiece respirators, ambient and in-facepiece samples were collected on workers in foundry, aircraft-painting, and steel-manufacturing operations. Protection was assessed by workplace protection factors (WPF). The appropriateness of the assigned protection factor (APF) for half-facepiece respirators was evaluated with a new approach using the WPF data from these and other studies previously published. The new approach utilizes binomial statistics based on the number of successes (no overexposure) and failures (overexposure) and is illustrated with a graphical representation of WPF data. With this consideration of the data, the probability of overexposure occurring during a wearing period for workers wearing the half-facepiece respirators represented by the studies referenced here was 0.5%, with a 95% confidence interval of 0.01 to 2.7%. If 50% in-facepiece sampling errors are considered, the probability of overexposure was 2.9%, with a 95% confidence interval of 1.1 to 6.3%. The authors believe the current APF of 10 for half-facepiece respirators is appropriate.

**Keywords:** assigned protection factor, dust exposures, half-facepiece respirators, in-facepiece sampling, workplace protection factors

A series of studies was undertaken to evaluate the protection provided by dust/mist and dust/fume/mist, elastomeric and disposable, half-facepiece respirators. The workplace protection factor (WPF), a ratio of ambient and in-facepiece concentration, was calculated as an index of respirator performance.<sup>(1)</sup> The overall study protocol and the WPF results for foundry, aircraft-painting, and steel-manufacturing operations have been previously reported.<sup>(2-5)</sup>

In the foundry operations, workers' exposures to zinc and lead dusts and fumes were measured while they wore dust/fume/mist, elastomeric and disposable, half-facepiece respirators.<sup>(3)</sup> In the aircraft paint-spraying operations, exposures to metal pigments in paint overspray were evaluated during the use of elastomeric half-facepiece respirators

equipped with combination high efficiency filter and organic vapor cartridge air-purifying elements.<sup>(4)</sup> In the steel-manufacturing operations, workers' exposures to dusts were evaluated for various production processes while wearing dust/mist half-facepiece respirators.<sup>(5)</sup>

Several other field studies have also been conducted over the last 10-13 years to evaluate the appropriateness of the APF for negative pressure half-mask respirators.<sup>(6-13)</sup> Table I summarizes the exposure agents, ambient concentrations, in-facepiece concentrations, WPFs, and the fifth percentiles of the WPF distributions for these field studies. The smallest fifth percentile (2) was observed in Fergin's study.<sup>(7)</sup> Reed et al.<sup>(8)</sup> reported the second smallest fifth percentile (3) for a negative pressure half-mask dust respirator. Dixon and Nelson reported a much higher fifth

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TABLE I. Summary of Results from Different WPF Studies

Researchers <sup>A</sup>	Exposure Agents	Permissible Exposure Limit ( $\mu\text{g}/\text{m}^3$ ) <sup>B</sup>	N	Ambient		In-Facepiece		WPF		Range	Fifth Percentile
				GM ( $\mu\text{g}/\text{m}^3$ )	GSD	GM ( $\mu\text{g}/\text{m}^3$ )	GSD	GM	GSD		
Revoir (1974)	cotton	1,000	16	2780	2.1	103.0	3.2	27	2.0	8–83	9
Dixon & Nelson (1984)	lead	50	42	220	2.7	0.07	5.0	3360	4.8	53–35400	254
Fergin (1984)	aluminum	15,000	75	31,200	2.3	840.0	5.8	37	5.3	1–1040	2
Lenhart & Campbell (1984)	lead	50	25	580	3.3	3.2	3.8	182	4.0	10–2200	19
Reed et al. (1984)	total dust	15,000	19	14,900	2.2	800.0	2.7	18	3.1	5–150	3
Galvin et al. (1990)	styrene	426,000	63	375,000	1.8	4750.0	3.4	79	3.1	3–980	12
Wallis et al. (1993)	manganese	5,000	70	1400	4.0	27.0	2.5	51	3.4	3–850	7
Gaboury et al. (1993)	benzo(a)pyrene	200	18	800	1.8	17.0	3.2	47	2.5	13–410	11
Myers et al. (1996)	zinc	4,000	66	240	3.2	2.1	5.3	114	4.6	5–5450	9
Zhuang & Myers (1996)	chromium	1,000	15	1330	2.2	0.3	4.4	4960	5.4	305–16000	282
	titanium	9,000	21	980	2.8	0.3	2.6	3410	3.1	101–45800	516
Myers & Zhuang (1998)	iron	10,000	51	1580	2.9	6.1	3.7	260	3.3	19–3990	37

<sup>A</sup> Revoir and Fergin did not perform any fit-test; Dixon, Galvin, and Wallis performed qualitative fit-tests; in the rest of the studies, quantitative or qualitative fit-tests were performed before respirators were used.

<sup>B</sup> The permissible exposure limits for zinc and titanium are based on their atomic weight fraction of oxide molecular weights.

percentile of 160 (reported as 254 in reference 18) in their study.<sup>(9)</sup> The largest fifth percentile (516) was reported by Zhuang and Myers<sup>(4)</sup> for aircraft paint-spraying operations.

The fifth percentile WPF values vary by more than an order of magnitude among these different studies. Of all the fifth percentiles estimated from the 11 studies, only 7 were greater than 10. If we consider each fifth percentile estimate as an independent observation, the mean and standard deviation for these fifth percentile observations are determined to be 97 and 165, respectively. The geometric mean (GM) and geometric standard deviation (GSD) are 22 and 6.1, respectively.

This article presents and discusses a new approach to evaluate the appropriateness of the APF. This new approach utilizes binomial statistics based on the number of successes (no overexposure) and failures (overexposure) and is illustrated with a graphical representation of WPF data.

## BACKGROUND

In 1983 Myers et al.<sup>(14)</sup> first suggested using WPF data, when available, instead of fit-factor data as the basis for setting respirator class APF values. Several approaches were suggested where the respirator class APF level would be based on the lower fifth percentile estimate of a WPF distribution or on the one-sided lower tolerance limit value above which the WPF values would be predicted to lie with a specific confidence level, such as 95%. Much discussion about how to evaluate “correctly” and employ WPF data collected from a variety of workplaces and exposure agents to set class APF values has followed and continues to occur. Recently, Nicas<sup>(15)</sup> employed a statistically rigorous approach for reducing and evaluating WPF data when it is to be used to set a respirator class APF value.

While these approaches differ in how they suggest WPF data be analyzed and applied in this APF value setting process, they all arrive at a common end point—a class APF value at which a certain level of confidence exists that future users will obtain at least the APF level of protection in the workplace. From a standards-setting point of view, those WPF data analysis techniques that result in the lowest estimates of APF level could be more appropriate because a higher confidence would exist that a respirator user would achieve a WPF greater than the respirator’s class APF.

However, this argument is confounded by the fact that WPF is a secondary measure of protection. The primary assessment of protection must be based on the comparison of in-facepiece concentration (Ci) and the exposure standards such as the permissible exposure limit (PEL), threshold limit value (TLV<sup>®</sup>), etc. If the in-facepiece concentration of a contaminant is below the exposure standard for that contaminant, then the respirator provides the worker with adequate protection regardless of the corresponding WPF value. The question then becomes what is the appropriate APF level that assures an overexposure will not occur during a wear period with a given certainty, rather than what is the appropriate APF level that the WPF value will exceed with a given certainty.

## METHODS

### Graphical Approach for Representing WPF Data

The importance of assessing protection based on the comparison of Ci and PEL is graphically illustrated for different WPF versus APF scenarios in Figure 1. This figure has as its x-axis ambient contaminant concentration (Co) normalized by its PEL (any other exposure standard value could be substituted for the PEL). When normalized by PEL, this ratio (called “hazard ratio” in the American National Standards Institute standard Z88.2<sup>(16)</sup>) represents the minimum required level of protection that a respirator would need to provide. The y-axis is the WPF (Co/Ci) provided by the respirator. Line AB represents the values that satisfy the condition  $\text{WPF} = \text{Co}/\text{PEL}$  between 1 and 1000. Since  $\text{WPF} = \text{Co}/\text{Ci}$ , line AB represents observations where  $\text{Co}/\text{Ci} = \text{Co}/\text{PEL}$  or  $\text{Ci} = \text{PEL}$ . That is the set of points where the WPF provided by the respirator exactly equals the amount of protection required. An observation falling to the left of this line would represent a condition where the respirator provided a WPF greater than the minimum required, resulting in an in-facepiece concentration that would be less than the PEL. Therefore, the worker is not overexposed and receives adequate protection. An observation falling to the right of this line would represent a condition where the respirator provided a WPF that was less than the minimum that is required. The in-facepiece concentration would be greater than the PEL, and therefore the worker would receive inadequate protection and be overexposed.

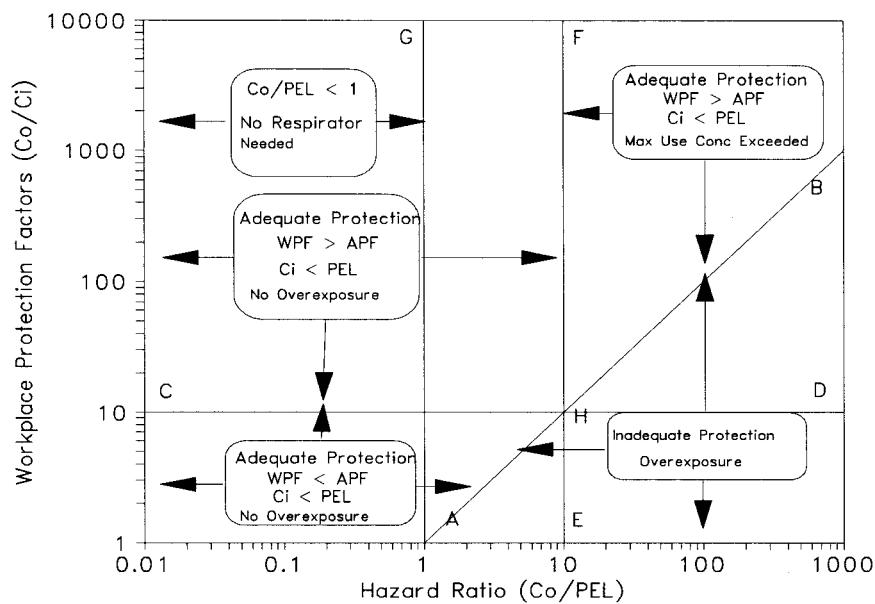


FIGURE 1. Illustration of different conditional outcomes when WPF is plotted against hazard ratio relative to an assigned protection factor of 10 and maximum use concentration of  $10 \times$  permissible exposure limit

Line CD represents the APF of 10 for half-facepiece respirators. A WPF observation falling below this line does not necessarily mean overexposure but rather it represents possible overexposure. The failure of the respirator to provide a WPF greater than 10 results in an overexposure only when the WPF observation falls below Line CD and to the right of Line AB. A WPF observation falling below Line CD and to the left of Line AB does not result in overexposure even if the WPF is less than 10.

Line EF represents the half-facepiece respirator maximum use concentration of  $10 \times$  PEL. Ambient concentrations to the right of Line EF exceed  $10 \times$  PEL, and therefore represent exposure conditions over the maximum use limit for half-facepiece respirators. Normalized concentrations, i.e., hazard ratio, falling between 1 and 10 represent suitable exposure concentrations for using half-facepiece respirators. Hazard ratios falling below 1 (Line AG) represent exposure concentrations where no respirator use is required. The point H is the intersection of Lines AB, CD, and EF.

By this graphical representation, it is easily seen that the failure of the respirator to provide a WPF greater than 10 results in an overexposure during the wear period only when the WPF observation falls below Line CD and to the right of Line AB and to left of Line EF. This area is the triangle AHE. Workplace protection factors that fall below Line CD and to the left of Line AB do not result in worker overexposure during the wear period. Observations falling above Line CD and to the right of Line EF and to the left of Line AB represent conditions where the respirator was used in contaminant levels exceeding the maximum use concentration of  $10 \times$  PEL, yet the WPF provided was still adequate to keep the in-facepiece concentration below the PEL, resulting in no overexposure to the worker. Observations falling to the right of Line EF and to the right of Line AB represent conditions where the respirator was used in maximum use concentrations exceeding  $10 \times$  PEL, and the WPF it provided was inadequate resulting in an overexposure (i.e.,  $C_i > \text{PEL}$ ) to the worker.

As an example, the WPF observations for the steel mill operations<sup>(5)</sup> were plotted against the corresponding hazard ratios in Figure 2. No single observation was found under either Line AB

or Line CD from the figure. Two observations fall in the area between a hazard ratio of 1 and 10. The remaining 49 observations lie to the left of line AG, where the hazard ratio is less than 1. The respirators appeared to have provided adequate protection, and there was no overexposure.

### Probability Estimates Using Binomial Statistics

Given that an observation falls between Lines AG and EF, the observation can be classified into two categories: success and failure. A success (no overexposure during the wear period) is defined as an observation falling within the trapezoid AGFH. A failure (overexposure during the wear period) is defined as an observation falling within the triangle AEH. The WPF data were obtained from different studies with different contaminants and with different respirators. Each observation is considered to be independent. The probabilities of success and failure for these different classes (contaminants, respirators, and workplaces) may be different. Practically, these differences are considered to be negligible.

The probability of success ( $p$ ) is estimated to be the number of observations within trapezoid AGFH divided by the total number of observations within rectangle AGFE. The probability of failure ( $q$ ) is estimated to be one minus the probability of success or the number of observations within triangle AEH divided by the total number of observations within rectangle AGFE. The binomial probability distribution function (PROBBNML) of the Statistical Analysis System (SAS®; SAS Institute Inc., Cary, N.C.) was used to determine the 95% confidence intervals of the probability estimates of success and failure.

### Evaluation of the Adequacy of APF

The graphical approach can also be used to evaluate the appropriateness of existing APF levels. The range for applicable respirator use is first defined. Then the number of observations in different areas is determined. The probabilities for success (no overexposure during the wear period) and failure (overexposure during the wear period)

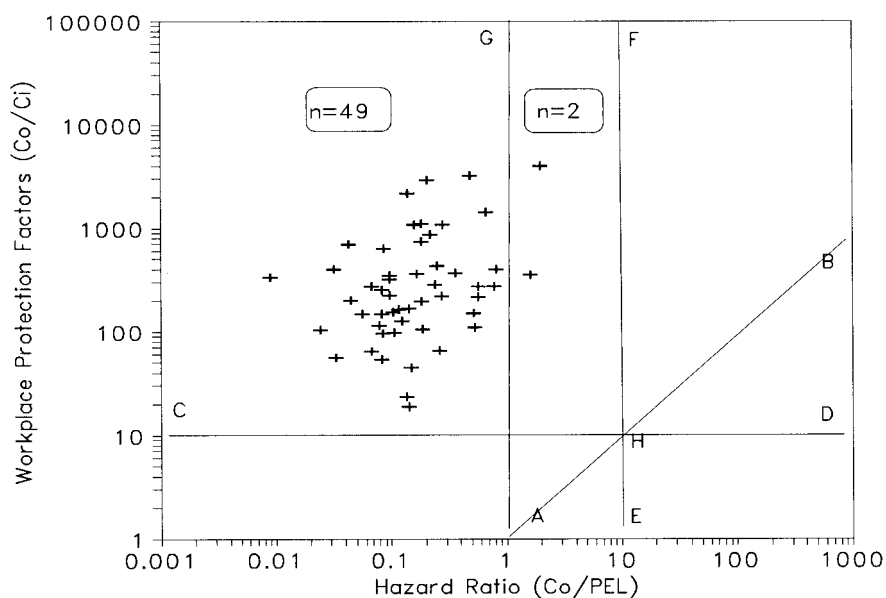


FIGURE 2. Plot of WPFs for steel mill operations against hazard ratios

are estimated. The appropriateness of the current APF can be determined by comparing the probability of overexposure in a wear period with the acceptable risk for overexposure. If the probability of overexposure satisfies the acceptable risk for overexposure, the APF is appropriate. Otherwise, it is not appropriate.

## RESULTS AND DISCUSSION

### Graphical Representation of Combined WPF Data

The WPF observations from the 11 published studies were plotted against the corresponding hazard ratios in Figure 3.<sup>(3-5,9-16)</sup> Of the 481 total observations in Figure 3, 256 (53.2%) fall to the left of Line AG (237 with  $WPF \geq 10$  and 19 with  $WPF < 10$ ); 204 (42.4%) fall between Lines AG and EF (188 with  $WPF \geq 10$ , 15 with  $WPF < 10$  and  $WPF \geq Co/PEL$ , and 1 with  $WPF < Co/PEL$ ); and 21 (4.4%) fall to the right of Line EF (20 with  $WPF \geq Co/PEL$  or above Line AB, and 1 with  $WPF < Co/PEL$ ). Two WPF observations fell under Line AB, indicating that in-facepiece concentration exceeded the PEL.

Considering the WPF data in Figure 3, two observations are apparent. Of the 481 WPF measurements extracted from these 11 published studies, 276 of the WPF's determinations, approximately 57%, were made from ambient concentrations that were actually less than the PEL. That is, the hazard ratio was less than one. Therefore, a substantial number of the times the half-facepiece respirators were used, the exposure concentrations actually existing suggest they were not needed.

The second observation is that 21 (approximately 10%) of the 205 WPF data points having a hazard ratio greater than 1 fell into the rectangle bordered by FHD. These data points represent the WPF observations that occurred when the half-facepiece respirators were used in ambient exposure concentrations that exceeded the maximum use concentration appropriate for this class of facepiece. That is, the hazard ratio was greater than 10. This illustrates how difficult it is, even for well-trained industrial hygienists, to adequately characterize ambient exposure conditions that in-

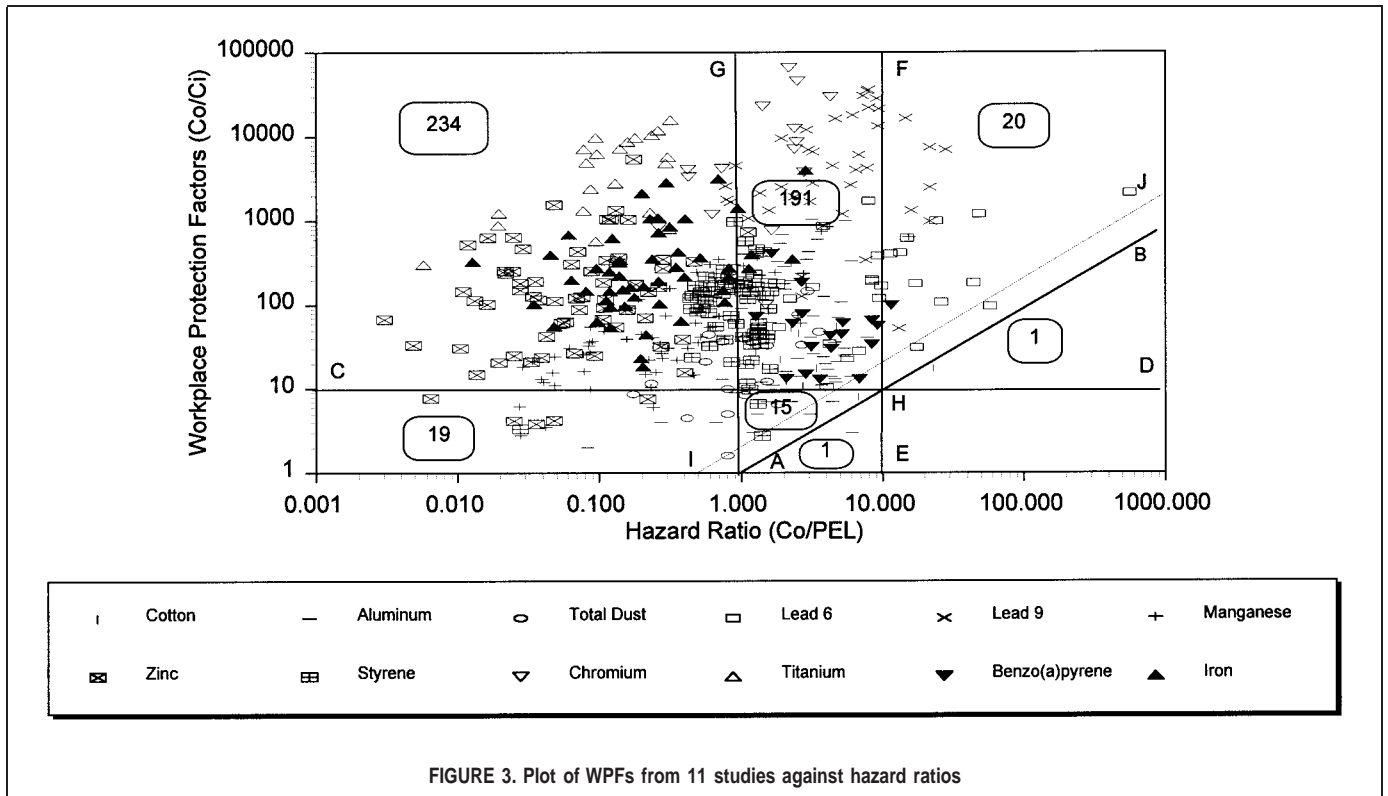
dividual workers may experience due to naturally varying ambient concentrations, varying locations from point sources, personal work practices, etc.

When all 481 WPF observations were used, the GM and GSD were 136 and 8.1, respectively. The fifth percentile is estimated to be 4. When only the WPF observations with hazard ratios between 1 and 10 were used, the GM and GSD were 133 and 10.2, respectively. The fifth percentile is estimated to be 3. These results are quite different from those reported by Nelson.<sup>(17)</sup> Nelson considered several half-mask respirator studies (some not published in peer review journals) that the present authors did not, to obtain a data set with 390 observations. In addition, in the current study WPF data obtained from studies that did no fit testing were not rejected. Of these 390 data points, the GM is estimated at 290, with a GSD of 6.5. The best estimate of the fifth percentile is 13, with a 95% confidence interval of 10 to 18. The issue of which studies to combine is critical in evaluating the appropriateness of the APF for half-mask respirators. Large GSD is also one of the reasons why the fifth percentile estimate is low. Thus, the combined data in this study are evaluated using probability estimates for a binomial distribution as follows.

### Probability Estimates Using Combined WPF Data

Based on the data used to construct Figure 3, the estimate of  $p$  (no overexposure during the wear period) is  $204/205$  or 0.9951, and  $q$  (overexposure during the wear period) is estimated to be  $1/205$  or 0.0049. The 95% confidence intervals are 0.9731–0.9999 for  $p$  and 0.0001–0.0269 for  $q$ . As more data are added to this data set, these estimates of  $p$  and  $q$  may be expected to demonstrate some variability. However, as the data set becomes larger, the estimates of  $p$  and  $q$  become more stable.

Line AB can also be adjusted to consider inaccuracy in collecting in-facepiece samples. We know that streamlining of air and aerosol within a respirator during the inhalation portion of the respiratory cycle is a significant source of in-facepiece sampling bias. Such streamlining leads to nonuniform distributions of contaminant within the respirator. A study by Myers et al. utilized



acetone as a challenge agent to document in-mask sampling biases ranging from -98% to +98%, with a mean bias of -17%.<sup>(18)</sup> The location of air streamlines relative to the position of the sampling probe was thought to contribute to the observed sampling bias. This factor reduces aerosol migration from the mask cavity to the sampling probe and causes an understatement of aerosol penetration and a subsequent overestimation of respirator protection. In addition, lung deposition,<sup>(19)</sup> line losses from probe inlet to sampling cassette, and nonrepresentative sampling within the facepiece are other sources of bias. If all sources of bias are considered and a mean bias of 50% is assumed, Line IJ (instead of Line AB) in Figure 3 represents the set of points where the WPF provided by the respirator equals the amount of protection required. Line IJ represents observations where  $Co/(2Ci)=Co/PEL$  because the actual in-facepiece concentration is equal to two times the original concentration due to a bias of 50%. Now nine observations were found under Line IJ (equivalent to Line AB) from Figure 3. Of these nine observations, three observations fall to the left of Line AG (where  $Co/PEL < 1$ ) or to the right of Line EF (where  $Co/PEL < 10$ ), and six observations fall between Lines AG and EF. The estimate of  $p$  is now  $199/205$  or  $0.9707$ , and  $q$  is estimated to be  $6/205$  or  $0.0293$ . The 95% confidence intervals are  $0.9374-0.9892$  for  $p$  and  $0.0108-0.0626$  for  $q$ .

### Adequacy of the Current APF of 10

The probability of overexposure occurring during a wearing period for workers wearing the half-facepiece respirators represented by the 11 studies referenced here was 0.5%, with a 95% confidence interval of 0.01 to 2.7%. If we consider an average 50% in-facepiece sampling error (i.e., a safety factor of two), the actual in-facepiece concentration is equal to two times the measured concentration. In other words, no overexposure occurs or is declared if the in-facepiece concentration is less than or equal to one half of the PEL. Assuming a 50% in-facepiece sampling error, the prob-

ability of overexposure increases from 0.5 to 2.9%, with a 95% confidence interval of 1.1 to 6.3%.

If the acceptable risk is defined, the question regarding the appropriateness of the current APF for half-facepiece respirators can be answered right away. Unfortunately, such a risk has not been defined. The authors encourage the respirator community to think about and discuss what is an acceptable level of risk. Based on professional judgment, the authors believe the probability estimates (0.5 or 2.9% with a safety factor of two) may be acceptable. If so, then the current APF of 10 for half-facepiece respirators seems to be appropriate.

### Impact of Changes in PEL on Worker Protection

The graphical representation can also be used to evaluate the impact on the protection provided by a respirator when a PEL is changed. The WPFs for the steel mill operations were replotted against hazard ratios ( $Co/PEL$ ) in Figure 4 for a situation where there is a 50% reduction in PEL. It can be seen from the figure that the horizontal coordinates shift to the right, whereas vertical coordinates remain unchanged. No single observation was found under either Line AB or Line CD from the figure again. However, nine observations fall in the area between hazard ratios of 1 and 10. The remaining 42 observations lie to the left of Line AG where hazard ratio is less than 1. In this contrived scenario, if the PEL was lowered by one half, the respirators would still provide adequate protection and there would be no overexposure.

## SUMMARY AND CONCLUSIONS

Utilizing a graphical representation of WPF data and binomial statistics based on the number of successes (no overexposure) and failures (overexposure), the appropriateness of the current APF of 10 for half-facepiece respirators was evaluated. With this

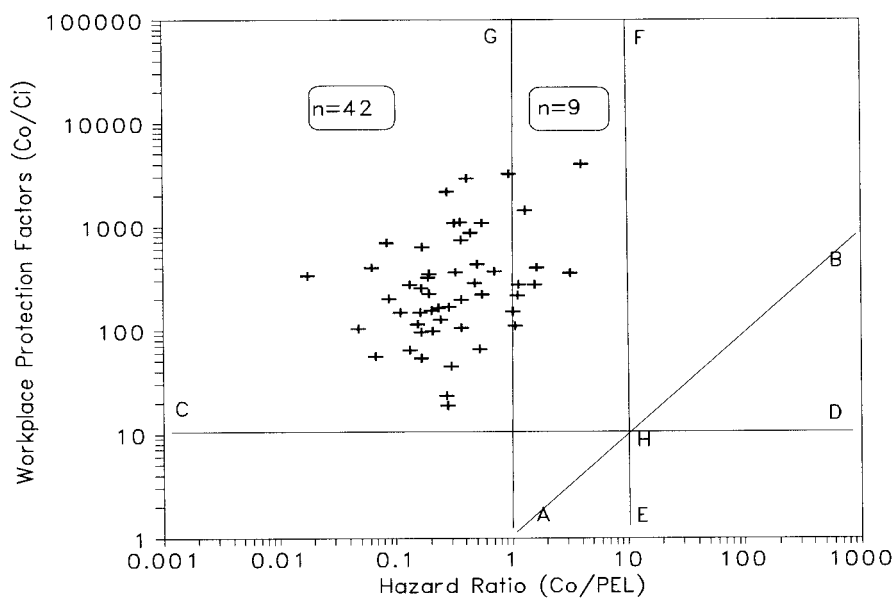


FIGURE 4. Replot of Figure 2 assuming the PEL is reduced by one half

consideration of the data, the probability of overexposure occurring during a wearing period for workers wearing the half-facepiece respirators represented by the studies referenced here was 0.5%, with a 95% confidence interval of 0.01 to 2.7%. Said in another way, workers wearing these half-facepieces had a probability of 99.5% of not being overexposed during a single wearing period. If we consider in-facepiece sampling errors of 50%, the probability of overexposure was 2.9%, with a 95% confidence interval of 1.1 to 6.3%. The authors believe the current APF of 10 for half-facepiece respirators is appropriate.

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