

Industrial Hygiene Principles and the Use of Assigned Protection Factors

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ABSTRACT

This analysis describes the application of industrial hygiene concepts to the evaluation of air contaminant exposures of workers using half facepiece respirators. The use of the assigned protection factor in estimating in-respirator exposure is illustrated, along with appropriate comparisons to occupational exposure limits. A Monte Carlo simulation incorporating workplace lead concentrations and respirator workplace protection factors is used to model time-weighted average respiratory protection and estimate the likelihood of overexposure to lead. The analysis indicates that half facepiece respirators provide very good respiratory protection when properly selected and worn. The use of the lower 5th percentile of the aggregate workplace protection factor distribution to set assigned protection factors is supported by the analysis.

Keywords: Respirator, protection factor, APF, WPF

INTRODUCTION

Respiratory protection is frequently used to control worker exposures to air contaminants. Those responsible for choosing respirators may include industrial hygienists, safety managers, engineers, site managers and others. Any of these individuals engaged in the respirator selection process may not fully appreciate its industrial hygiene aspects. The industrial hygiene profession (also called occupational hygiene and occupational health) includes the control of exposures to air contaminants to levels which reduce the risk of sensory irritation and occupational disease. Engineering methods, including process enclosure or local exhaust ventilation, are the preferred means to control these hazards. Respiratory protection is used as a temporary control measure or when more permanent controls are not feasible. In either case, the practitioner's task is to reduce exposures that are considered unacceptable to levels that are considered acceptable. Occupational exposure limits (OEL) are the guidelines used to determine acceptable exposures and estimate the degree of exposure reduction that is required.

When respiratory protection is used for exposure reduction, it must be properly selected, maintained and used in the context of a comprehensive respiratory protection program (CFR, 2007b; BSI, 1997). This paper will focus on a single program component: the use of the assigned protection factor (APF) to estimate the degree to which air contaminant exposures have been reduced by respiratory protection.

APF DEFINITION AND USES

Numerous definitions of APF are found in the literature (ANSI, 1992; NIOSH, 2005; BSI, 1997). All are generally similar to that used by the U.S. Occupational Safety and Health Administration (OSHA): ". . . the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program as specified by this section (CFR, 2007b).

APFs represent a way to estimate the amount of air contaminant exposure reduction necessary for a properly selected, fitted and used respirator to protect the wearer. The measured or estimated contaminant concentration outside the respirator (C_o) is divided by the maximum concentration permissible in the wearer's breathing zone (C_i). The highest acceptable exposure inside a respirator is known as the occupational exposure limit (see definition below). Therefore, in the selection process this value is used to represent C_i :

$$\frac{C_o}{C_i} = \frac{\text{Workplace exposure concentration}}{\text{Exposure limit}} = \text{APF needed} = \text{Hazard Ratio} .$$

A respirator with an APF equal to or greater than the Hazard Ratio must be selected.

APFs are also used to determine the maximum use concentration (MUC) for respirators or classes of respirators to be used within a specific environment. The intended and appropriate use of both APF and MUC are found in the definition of MUC: ". . . the maximum atmospheric concentration of a hazardous substance from which an employee can be expected to be protected when wearing a respirator, and is determined by the assigned protection factor of the respirator or class of respirators and the exposure limit of the hazardous substance" (CFR, 2007b) Thus:

$$\text{MUC} = \text{APF} \times \text{Exposure limit}.$$

The APF relationship can also be rearranged algebraically to provide an estimate of C_i for a properly selected, maintained and used respirator with a stated APF when used in a known ambient exposure concentration:

$$\frac{C_o}{\text{APF}} = C_i$$

A respirator must have an APF sufficient to reduce the user's exposure from a C_o concentration above the exposure limit to a C_i concentration below the exposure limit. It can be seen that a respirator used at its MUC is at the limit of its ability to do this:

$$\frac{\text{MUC}}{\text{APF}} = \text{Exposure Limit}$$

These simple industrial hygiene concepts must not be overlooked when respirators are selected.

OCCUPATIONAL EXPOSURE LIMITS

Many organizations throughout the world recommend or enforce occupational exposure limits (ACGIH, 2003; CFR, 2007a; DFG, 2007). OELs are generally established to represent conditions under which it is believed nearly all workers may be repeatedly exposed without adverse health effects. However, OELs in themselves do not sharply delineate between safe and unsafe exposures (ACGIH, 2003).

The great majority of exposure limits for air contaminants are 8-hour time-weighted average (TWA) values. Therefore, airborne exposures above the TWA limit are acceptable if they are sufficiently compensated by exposures below the limit during the workday (ACGIH, 2003). Time-weighted average exposures are calculated using the following formula:

$$TWA = \frac{C_1 T_1 + C_2 T_2 + \dots + C_n T_n}{T_1 + T_2 + \dots + T_n}$$

Where C = the contaminant concentration for a given time period and
T = duration of a given time period

For example, assume a dust has an 8-hour TWA exposure limit of 100 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$). Air sampling reveals a worker has the following exposures during the day:

2 hours at 150 $\mu\text{g}/\text{m}^3$
1 hour at 200 $\mu\text{g}/\text{m}^3$
3 hours at 50 $\mu\text{g}/\text{m}^3$
2 hours at 30 $\mu\text{g}/\text{m}^3$

The TWA exposure calculation is:

$$TWA = \frac{(150 \times 2) + (200 \times 1) + (50 \times 3) + (30 \times 2)}{2 + 1 + 3 + 2} = \frac{710}{8} = 89 \mu\text{g}/\text{m}^3$$

Since the TWA exposure is below the exposure limit of 100 $\mu\text{g}/\text{m}^3$ (assuming the sampling and analytical methods have acceptable variability), the worker's exposure does not exceed the exposure limit and is considered acceptable.

Now assume a different worker has the following exposures to the same dust:

2 hours at 500 $\mu\text{g}/\text{m}^3$
2 hours at 1200 $\mu\text{g}/\text{m}^3$
2 hours at 150 $\mu\text{g}/\text{m}^3$
2 hours at 80 $\mu\text{g}/\text{m}^3$

This worker's TWA exposure is:

$$TWA = \frac{(500 \times 2) + (1200 \times 2) + (150 \times 2) + (80 \times 2)}{2 + 2 + 2 + 2} = \frac{3860}{8} = 482 \mu\text{g}/\text{m}^3$$

This worker's TWA exposure exceeds the OEL and must be reduced. Ultimately, this exposure should be controlled with engineering methods. Additionally, while those controls are being designed and installed,

the worker must be protected. An appropriately selected respirator used in conjunction with a well-implemented respiratory protection program is often the most acceptable option.

The shorter duration exposure limits that are in place for some contaminants must also be considered. In the U.S., some of the substances for which 8-hour TWA limits exist also have a short-term exposure limit (STEL). In these cases, the STEL represents a 15-minute TWA that should not be exceeded during the workday, regardless of whether or not the 8-hour TWA exposure exceeds that limit (ACGIH, 2003). Fewer substances have only a ceiling limit (C), which represents a concentration that should never be exceeded at any point during the workday, without respect to duration. Both STEL and C limits are in place to address potential adverse effects of short duration exposures, such as irritation or dose-rate dependent toxic effects (ACGIH, 2003). The application of APFs shown above applies to STEL and C limits as well as 8-hour TWA limits.

RESPIRATOR SELECTION

In the case of the overexposed worker in the above example, the hazard ratio is:

$$\frac{C_o}{C_i} = \frac{482 \mu\text{g}/\text{m}^3}{100 \mu\text{g}/\text{m}^3} \approx 5$$

Thus, a respirator with an appropriate filter and an APF of five or greater must be selected. If it is assumed a half facepiece with N95 filtration (APF=10) is selected and properly used, the worker's expected maximum exposure inside the respirator can be estimated by applying the APF relationship as follows:

$$C_i = \frac{C_o}{\text{APF}} = \frac{482 \mu\text{g}/\text{m}^3}{10} = 48 \mu\text{g}/\text{m}^3$$

Thus, with a properly fitted and used respirator, the worker's estimated inhalation exposure has been reduced to a maximum estimate less than half the TWA exposure limit of $100 \mu\text{g}/\text{m}^3$.

ANALYSIS OF C_i ESTIMATES AND MODELING C_i EXPOSURES

The estimated exposure inside the respirator (C_i) calculation shown above actually uses a shortened form of the worker's entire exposure profile for the day. The full calculation using the APF is:

$$C_i = \frac{\frac{(500 \times 2)}{10} + \frac{(1200 \times 2)}{10} + \frac{(150 \times 2)}{10} + \frac{(80 \times 2)}{10}}{2 + 2 + 2 + 2} = \frac{100 + 240 + 30 + 16}{8} = 48 \mu\text{g}/\text{m}^3$$

Note that the C_i exposure for the second sampling period is $240 \mu\text{g}/\text{m}^3$, which is numerically greater than the 8-hour TWA limit of $100 \mu\text{g}/\text{m}^3$. This does not mean the selected respirator is inadequate. *The 8-hour TWA concept applies when respirators are used as it would for situations in which respirators are not used.* The TWA C_i estimate in this example is well below the exposure limit and is acceptable. As noted earlier, periods of exposure above the TWA limit are tolerable if they are sufficiently compensated by exposures below the limit during the workday.

The data and methodology used to establish APFs are discussed in detail elsewhere (Nelson, 1996; Federal Register, 2006). In the U.S., OSHA set the APF for half facepiece respirators using performance data from workplace protection factor (WPF) studies (Federal Register, 2006). In a WPF study, C_o and C_i are measured simultaneously while workers perform their jobs using properly fitted and worn respirators (AIHA, 2002). In a WPF study (Weber and Mullins, 2000; Bidwell and Janssen, 2004; Janssen *et al.*, 2007) groups of 4 or 5 workers per day are typically sampled for several days. The WPF sample pairs are normally changed at the workers' break and lunch times, resulting in 3 or 4 sample sets per worker per day. The duration of each sample period is typically in the range of 45-120 minutes. Because both contaminant concentration (C_o) and respirator performance (reflected by C_i) vary during the workday, the result of a WPF study is typically a lognormal distribution of WPF values (see Figure 1). It is customary to judge a respirator's performance by the lower 5th percentile of the distribution of these short-term WPF samples, e.g., 19 for the half facepiece study shown in Figure 1 (Nelson, 1995; Weber and Mullins, 2000). That is, if the lower 5th percentile equals or exceeds the APF for the respirator's class (e.g., 10 for a half facepiece) the respirator's performance is considered adequate. Using similar logic, OSHA set the APF for half facepieces at 10, based on lower 5th percentiles of 12 and 18 for elastomeric and filtering facepieces, respectively (Federal Register, 2006).

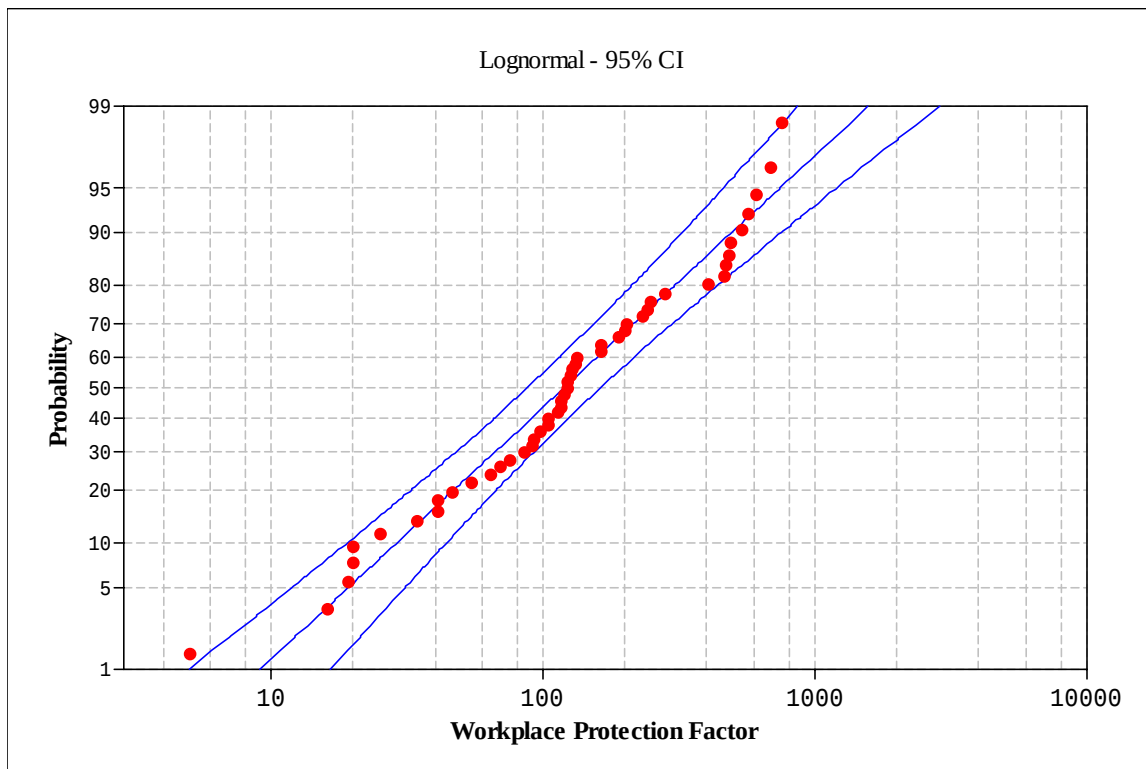


Figure 1. Probability plot of overall WPF distribution for a half facepiece (Janssen *et al.*, 2007).

Current use of the lower 5th percentile suggests that, in a population of individual WPF samples, 5% are expected to be less than the 5th percentile value. It *does not* suggest that 5% of workers will be over exposed to, or inadequately protected from the air contaminant. There are three reasons this is the case: 1) WPF distributions are based on a series of short-term measurements (several donnings per worker per day); 2) The vast majority of air contaminants with OELs have 8-hour TWA exposure limits; it is reducing the workers' exposures to concentrations below the TWA limit that is important; 3) For 95% of donnings, the WPF exceeds the lower 5th percentile value.

It is essential to recognize the duration of WPF samples when performing analyses of WPF data to recommend or judge the adequacy of APFs. WPF distributions describe the mean and variability of single, relatively short duration samples collected over the course of one or more work shifts. In themselves, individual WPF values or their distributions do not describe the ongoing protection a worker would receive from respirator use. As will be shown, appropriate, time-weighted averaging of WPF data must be done to make appropriate inferences about ongoing protection. This can be illustrated using a subset of the data OSHA analyzed to establish the APF of 10 for half facepieces.

The WPF and C_o data used to begin the analysis was taken from Exhibit 5-1, Appendix B, of the OSHA APF rulemaking docket (Docket H049C, 2002). Data chosen were limited to workplace studies of elastomeric half facepiece respirators tested against lead particles. This allowed the calculations to be done with a single exposure limit of $50 \mu\text{g}/\text{m}^3$. These data were also selected because OSHA found the entire elastomeric half facepiece data set had approximately 5% of its WPF values below 10, as implied when using the lower 5th percentile to set the APF.

Using the distributions of C_o and WPF in this data set, software (Oracle, 1996) was used to perform a Monte Carlo simulation resulting in an expanded distribution of each variable. A Monte Carlo simulation is a form of probability analysis that estimates possible outcomes from sets of random variables. A more thorough description of the process, as well as its use in respirator performance analysis has been published previously (Nelson, *et al.*, 2000). In the present study, the C_o and WPF distributions were generated randomly and randomly paired. The data shown in Tables I and II demonstrate that the modeled distributions were very similar to the original OSHA data. It is important to note that 20% of the OSHA and modeled C_o data exceed the 10X the MUC criterion for half facepieces.

Table I. OSHA and Modeled C_o Distributions

	OSHA C_o Data	Modeled Data
Number of C_o values	170	400
Geometric Mean ($\mu\text{g}/\text{m}^3$)	160	159
Geometric Standard Deviation	4.0	4.0
Lower 5th Percentile ($\mu\text{g}/\text{m}^3$)	16.4	16.8
% of C_o >10X exposure limit	20	20

The analysis resulted in 400 pairs of C_o and WPF. Each pair was assumed to represent a two-hour period of respirator use, equivalent to the duration of typical WPF samples. Thus, four pairs of C_o /WPF could be used to predict an 8-hour TWA C_i exposure to lead an individual would be expected to receive:

$$\frac{C_o}{\text{WPF}} = C_i$$

A time-weighted average WPF for the day, designated WPF_{TWA} , was also calculated. In all, 100, 8-hour days were modeled and the geometric mean (GM), geometric standard deviation (GSD) and lower 5th percentile calculated for the resulting 100 values of C_o , C_i and WPF_{TWA} . These data represent 100

“person-days” of respirator use. That is, the data could be seen as one day’s work for 100 individuals in a respirator user population. Alternatively, they could be viewed as 100 days of work for one individual.

Table II. OSHA and Modeled WPF Distributions

	OSHA WPF Data	Modeled Data
Number of WPFs	170	400
Geometric Mean WPF	273	271
Geometric Standard Deviation	8.1	7.3
Lower 5th Percentile	9	10
% of WPFs <10	3.5	4.7
Range of WPFs	2->10000	2->10000

RESULTS AND DISCUSSION

The results of the TWA analysis are summarized in Table III. The lower 5th percentile WPF_{TWA} of 17 is well above the APF of 10 for half facepieces. The geometric mean TWA C_i exposure was 2.27 µg/m³ and the 95th percentile TWA exposure was 24.6 µg/m³, less than half the exposure limit of 50 µg/m³. These modeled data clearly suggest very good protective performance for half facepiece respirators, particularly in light of the fact that approximately 20% of the modeled TWA C_o exposures exceeded the nominal MUC of 10X the exposure limit. Table IV shows typical modeled C_o, WPF and resulting C_i exposures for five modeled person-days.

Eleven of 400 *individual* C_o/WPF combinations (2.75%) resulted in a C_i above the lead exposure limit of 50 µg/m³, but only 1 of 100 TWA protected exposures (1%) exceeded the 8-hour TWA. The C_i TWA for this person-day was 70 µg/m³; the TWA C_o was 636 µg/m³ (~13X the exposure limit) and the WPF_{TWA} was 9. The exposure profile and calculation for this day were as follows:

$$\text{Protected TWA} = \frac{\frac{(60 \times 2)}{17} + \frac{(1529 \times 2)}{6} + \frac{(108 \times 2)}{2079} + \frac{(848 \times 2)}{42}}{2 + 2 + 2 + 2} = \frac{7.1 + 510 + 0.1 + 40}{8} = 70 \mu\text{g}/\text{m}^3$$

Note that the modeled WPFs *exceeded* 10 for 3 of the 4 exposure periods (17, 2079, 42). In addition, the C_o exposures for the second and fourth exposure periods were 30X and 17X the OEL, both in excess of the 10X MUC for half facepieces. Because C_o and C_i vary independently, a combination of high exposure (~30X the exposure limit) and less than expected respirator performance (WPF of 6) occurred during the same sample period. This combination is possible in actual workplaces, e.g., if the facepiece is momentarily dislodged during a period of high exposure. However, the overall analysis suggests this occurrence is infrequent and, in nearly all cases (99% in this exercise), adequately compensated by lower exposures and/or much better respirator performance. It is also important to recognize that, because C_o and WPF are expected to vary randomly in a properly fitted user population, the 1% of combinations that

result in a TWA C_i above the exposure limit would not routinely occur in the same person. In other words, the risk of repeated overexposure to an individual is extremely small. This further assures an individual's dose of a contaminant is minimized.

There has been some debate in recent years regarding the suitability of using APFs based on the lower 5th percentile of aggregate distributions of WPFs (Nicas and Neuhaus, 2004; Crump, 2007). The former authors suggested that no more than 5% of respirator users in a population should have more than 5% of their WPF values below the APF. In order to satisfy these criteria, they recommended reducing the half facepiece APF from 10 to 5. The model described in this paper demonstrates that, when WPFs are appropriately averaged and viewed in the context of industrial hygiene exposure control, the Nicas-Neuhaus criteria (and reduction of the APF) are unnecessarily conservative. Only 2% of modeled WPF_{TWA} were less than 10. Time-weighted average exposures to lead were maintained well below the exposure limit for 99% of the modeled person-days.

Table III. Summary of Modeled TWA Data

	TWA Data
<u>C_o TWA (n=100)</u>	
Geometric mean C _o (μg/m ³)	289
Geometric Standard Deviation	2.0
Lower 5 th Percentile C _o	90
% >10X exposure limit	20
<u>C_i TWA (n=100)</u>	
Geometric mean C _i (μg/m ³)	2.27
Geometric Standard Deviation	4.3
Lower 5 th Percentile	0.21
% > exposure limit	1
<u>WPF_{TWA} (n=100)</u>	
Geometric Mean	128
Geometric Standard Deviation	3.5
Lower 5 th Percentile	17
% of WPF _{TWA} <10	2
Range	9-7529

Table IV. Data by Donning for Five Person-Days

Person		Donning Number				TWA C _i ($\mu\text{g}/\text{m}^3$)
		1	2	3	4	
1	C _o ($\mu\text{g}/\text{m}^3$)	57	86	201	113	
	WPF	1015	>10000	231	2580	
	C _i ($\mu\text{g}/\text{m}^3$)	0.06	0.008	0.87	0.04	0.24
2	C _o ($\mu\text{g}/\text{m}^3$)	547	75	30	403	
	WPF	751	1992	822	873	
	C _i ($\mu\text{g}/\text{m}^3$)	0.73	0.04	0.04	0.46	0.32
3	C _o ($\mu\text{g}/\text{m}^3$)	564	537	379	1651	
	WPF	126	2929	1328	505	
	C _i ($\mu\text{g}/\text{m}^3$)	4.49	0.18	0.29	3.27	2.06
4	C _o ($\mu\text{g}/\text{m}^3$)	934	44	163	143	
	WPF	181	517	128	1243	
	C _i ($\mu\text{g}/\text{m}^3$)	5.17	0.08	1.27	0.11	1.66
5	C _o ($\mu\text{g}/\text{m}^3$)	94	119	26	865	
	WPF	115	70	643	85	
	C _i ($\mu\text{g}/\text{m}^3$)	0.81	1.70	0.04	10.12	3.17

The results of this exercise are in general agreement with those of Myers and Zhuang (1998) and Nelson *et al.* (2000). The former constructed a model which predicted a probability of overexposure during a single wearing period of 0.5% (95% confidence interval 1.1-6.3%). The Nelson *et al.* study used worst case distributions of C_o , WPF, and possible respirator defect (exhalation valve) leakage to model the probability of users having a C_i exposure above the exposure limit. They concluded the probability was low, with a worst case maximum of 6.8% of short duration C_i above the exposure limit. The highest long term mean C_i was predicted to be 29% of the OEL.

CONCLUSIONS

Respiratory protection is intended to reduce air contaminant exposures from levels considered unacceptable to levels considered acceptable. Exposure limits are used as guidance to define acceptability. Basic understanding of industrial hygiene principles, exposure limits and the APF concepts discussed earlier are necessary to appropriately apply and evaluate respiratory protection as an air contaminant exposure control.

Because the great majority of OELs are 8-hour TWA values, appropriate analyses of WPF data must recognize the WPFs as the relatively short duration measurements they are. It is TWA protection that is important. This particular modeling exercise was based on aggregate WPF data and demonstrated very good performance for half facepiece respirators. The current practice of setting APFs such that they are at or below the lower 5th percentile value of short duration WPF distributions is appropriately conservative. This model supports the APF of 10 for half facepiece respirators.

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