

Interpretation of Inhalation Airflow Measurements for Respirator Design and Testing

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ABSTRACT

Recent studies and much debate have focused on quantifying the airflow requirements of respirator users, particularly under conditions of very high to maximal work rates. It is often assumed that respirators and their components must be tested at flow rates that closely match these measurements to assure protection to users. This overly simplified assumption ignores the differences between laboratory tests and the workplace conditions in which respirators are used. While respirators and their components could be designed to comply with any airflow requirement, any change in performance requirements must first be evaluated to ensure it does not decrease workplace performance or user comfort. This paper suggests appropriate use of airflow measurements in setting respirator performance criteria and evaluating user protection. Available data do not suggest a need for change in testing criteria at this time. There is no indication that respirators that meet current U.S. approval criteria or substantially similar tests need performance enhancement to provide acceptable protection.

Keywords: Airflow, respirator testing, inhalation airflow, flow rates

INTRODUCTION

A significant consideration in the design of all types of respiratory protective equipment is the volumetric flow rate at which the device must purify or supply air to the user. For some respirator types, these flow rates have been based on empirical data. Bloomfield and Greenburg (1933) measured silica dust concentrations outside and inside abrasive blasting helmets to determine that six cubic feet per minute (CFM) airflow was necessary to reduce worker exposures to acceptable levels. Similarly, Burgess and Reist (1969) recommended a minimum flow rate of four CFM for a powered air purifying respirator with a half facepiece. Their recommendation was based on maintenance of positive pressure in the facepiece, measured sodium chloride penetration less than 0.1% and maximum inspiratory airflow rate for an "average worker" based on data from Silverman et al. (1943). All three criteria assumed a moderate work rate of 415 kg-m/min (68 W). The recommendations of 4 and 6 CFM for tight-fitting and loose-fitting atmosphere supplying and powered air purifying respirators remain in U.S. respirator regulations to this day (CFR, 1995).

Other existing respirator performance requirements generally correspond to the volume of air workers would inhale per minute (minute ventilation [V_I]) at moderate to high work rates. The specific reasons for choosing these flow rates are often not clear. Particle filter certification is typically conducted at a continuous flow rate of 85 or 95 L/min; gas/vapor cartridge and canister testing is done at continuous flow rates corresponding to V_I values of 30-64 L/min (CEN, 2000a; CEN, 2000b; CFR, 1995). Because it is known that V_I and peak inspiratory flow rates (PIF) exceed these values at higher work rates, it has

been suggested that greater test flow rates are necessary to assure adequate respirator performance. The concerns typically expressed are as follows:

- 1) Increased flow may increase penetration of particles through filters (Caretto et al., 2004, Kaufman and Hastings, 2005);
- 2) Penetration of gaseous contaminants through carbon beds may increase because of inadequate residence time (Osmond and Phillips, 2001);
- 3) High volumes of air breathed through a filter or carbon bed may result in rapid loading (Kaufman and Hastings, 2005); and
- 4) Positive pressure respirators may be "overbreathed" (drawn into negative pressure) at higher work rates, potentially exposing the wearer to increased inward leakage (Dahlback and Novak, 1983; Wilson et al., 1989).

Respirators and their components could be designed to comply with any airflow requirement, should a need be identified. Higher flow rate requirements could involve the penalty of increased size, breathing resistance or cost with no measurable benefit to the wearer. Indeed, larger respirators or those with higher breathing resistance may be less acceptable to wearers, reducing wear time. It is also important to note that no deficiencies in the protection provided by currently approved devices (when correctly selected, fitted and used) have been reported in the peer-reviewed literature. Furthermore, no correlation between respiration at high work rates and deficient protection has been established. Silverman et al. (1943) *assumed* that respirator test flow rates must match flow rates measured at heavy workloads to assure protection: "The (flow rate) data obtained show that the present flow standards for rating and testing canisters are inadequate." While this assumption may appear logical, it has not been critically evaluated.

The studies by Silverman et al. (1943) are still among the most comprehensive reports addressing the respiratory needs of individuals under varying work rate and breathing resistance conditions. While the studies have been criticized because of their age and homogeneous subject population (mostly young men), very little comparable data have been reported in recent years. Rather, recent studies generally focus on the effects of using a respirator on respiration or another physiologic measurement (Wilson et al, 1989; Johnson et al., 1999; Caretti et al., 2001).

For these reasons a study was undertaken to update the "baseline" respiration measurements reported by Silverman et al. "Baseline" measurements are those made on subjects not wearing respirators. A comprehensive description of the study's methods and results are reported in a companion paper (Anderson et al., forthcoming). This paper will be limited to discussion of the interpretation and use of these and other airflow measurements to assure acceptable respirator performance.

METHODS

Subjects

Fifteen healthy subjects (9 male, 6 female) were randomly selected from a pool of fifty-four 3M Company employee volunteers to participate in the study. After data collection was completed, 2 subjects were removed from the sample due to equipment malfunction during recording. The remaining thirteen subjects (8 male, 5 female) ranged in age from 20-65 years (43.8 mean, +/-13.1 SD). Prior to being accepted for the study, subjects were required to pass the American College of Sports Medicine's Physical Activity Readiness Questionnaire (PAR-Q) (ACSM, 2000). Subjects were asked not to make any changes in their regular level of physical activity during the study period. Participants' physical characteristics are summarized in Table I. All participants volunteered with informed consent. The study was approved by both the University of Minnesota's and 3M Company's Institutional Review Boards.

Equipment

Pulmonary gas exchange was measured using a breath-by-breath automated gas analysis system (CPX/D) with a disposable preVent pneumotach flowmeter (MedGraphics, St. Paul, MN). The CPX/D system's airflow measurement was calibrated before each test, both in relation to volume and flow by

means of a 3-L capacity syringe (Hans Rudolph, Kansas City, MO). In addition, the gas measurements were calibrated. Standard protocol for proper calibration provided by the manufacturer was followed. Previous work has shown this system provides both reproducible and reliable airflow measurements (Porszasz et al., 1994, Walschlager et al., 1996).

Two separate software applications were used during this study. Breeze Suite 6.1 (MedGraphics, St. Paul, MN) was used to monitor the metabolic state of the subjects through breath-by-breath analysis. The other application was custom designed DataLogger software (MedGraphics, St. Paul, MN), which allowed for the capture of airflow with a sampling rate of 100 Hz. The resolution of airflow measurements for the DataLogger software is a reported 8.64 ml/sec as provided by the manufacturer.

Table I. Participant characteristics

	Men			Women			Total		
	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
Age (years)	44.3	20.0	65.0	43.0	26	50	43.8	20.0	65.0
Height (m)	1.84	1.78	1.96	1.69	1.63	1.78	1.78	1.62	1.96
Weight (kg)	84.1	75.0	91.8	71.0	61.8	90.9	79.1	61.8	91.8
VO ₂ (ml/kg/min) ^{max}	41.2	31.6	49.6	31.8	28.0	36.9	37.6	28.0	49.6

Protocol

Subjects participated in a maximal graded exercise test until exhaustion to determine their maximal aerobic capacity (VO_{2max}). The VO_{2max} is the criterion measure of an individual's cardiorespiratory fitness, and is the product of the maximum cardiac output and arterial-venous oxygen difference (ACSM, 2000). From these results, the relative work effort necessary to elicit 40%, 60%, and 80% of each subject's VO_{2max} was estimated. These percentages of VO_{2max} were selected because they correspond with light, moderate, and heavy/vigorous workloads (Sharkey, 1977; Fox et al., 1993) and the metabolic work rates found in ISO 8996:2004 (2004). The calculations involved estimating the inclines at which 40%, 60%, and 80% of VO_{2max} occurred for each subject during their VO_{2max} baseline assessment. Workload levels were maintained at 40%, 60%, and 80% of the individual's VO_{2max} using methodology defined in previous work (Carette and Whitley, 1998; Johnson et al., 1999). The corresponding treadmill inclines were then used for each subject's three exercise test levels of light, moderate, and heavy work during the exercise testing.

Prior to the start of the exercise test, the procedure was explained, including how to report their Ratings of Perceived Exertion (RPE) using the Borg CR-10 scale (ACSM 2000). Subjects were given a 3-minute warm-up period in which the treadmill was set at 3.3 mph at 0% grade. The treadmill was then elevated to the subject's calculated incline from the baseline measurements that would elicit approximately 40% of VO_{2max} exercise effort. The subject was monitored during a 4-minute exercise session via the Breeze Suite 6.1 software to verify that approximately 40% of their VO_{2max} was attained, and that steady-state performance was achieved. After the 4-minute exercise period, the subject reported his or her RPE work rating. Concurrently, the subject's data was saved, and the Breeze Suite

6.1 software was disabled. The subject continued on the treadmill at the same speed and incline combination for two additional minutes. During this time, the customized MedGraphics DataLogger software application was enabled to acquire the subject's instantaneous inspiratory and expiratory airflows at a sampling rate of 100 Hz. The data sample was recorded and saved. The DataLogger software was then closed and the Breeze Suite 6.1 application reopened. The treadmill incline was then increased to the percent grade estimated to elicit 60% of the subject's VO_{2max} . The same procedures described above were followed for 60% of VO_{2max} and again for 80% of VO_{2max} . The total test duration was approximately 18 minutes.

Pulmonary gas exchange data was processed using the Breeze Suite 6.1 software. The following metabolic and subjective data was collected: VO_2 , heart rate, and RPE. Metabolic equivalent (MET) was calculated for each workload by dividing the VO_2 (ml/kg/min) at each workload by 3.5 (ACSM, 2000).

Instantaneous airflow data collected by the DataLogger acquisition software was processed using custom programming from MatLab 7 (The Mathworks, Inc., Natick, MA). The following is a detailed description of each dependent variable and how each was calculated within the two-minute sample:

- Minute ventilation (V_I), L/min: all instantaneous inspiratory airflows, that is all data points having positive airflow values, were summed and averaged across the 2-minute sample time.
- Maximum peak inspiratory airflow (PIF_{max}), L/min: the maximum positive airflow value within the entire two-minute sample.
- Mean peak inspiratory airflow ($\overline{PIF}$), L/min: the average of all the maximum positive airflows within each individual breath cycle.
- Breath frequency (F), breaths/min: the total number of breath cycles divided by two minutes.
- Mean tidal volume ($\overline{V_t}$), L/min: minute ventilation divided by the breath frequency.
- Mean inhalation time ($\overline{T_I}$), sec: the average of each breath's inhalation duration.
- Mean breath cycle time ($\overline{T_{tot}}$), sec: the average breath inhalation-exhalation cycle duration.
- Duty cycle (DC): the ratio of mean inhalation time to mean breath cycle time ($\overline{T_I} / \overline{T_{tot}}$).
- Volume of peak flow at 5% ($V_{peak \pm 5\%}$), L: within each individual breath cycle, the maximum positive airflow values were located. From these points within each breath cycle, two points along the inhalation curve were determined that were +/- 5% of each breath inhalation duration. The average flow within this region was calculated and the volume was computed.
- Volume of peak flow at 10% ($V_{peak \pm 10\%}$), L: similar process as $V_{peak \pm 5\%}$ except the criterion was +/- 10% of breath inhalation duration.
- Volume of peak flow at 25% ($V_{peak \pm 25\%}$), L: similar process as $V_{peak \pm 5\%}$ except the criterion was +/- 25% of breath inhalation duration.

Microsoft® Office Excel (Microsoft Corp., Redmond, WA) was used to calculate descriptive statistics for each dependent variable at each work rate. The statistics were calculated separately for each gender and for both genders combined. Normal probability plots were generated for PIF_{max} and V_I values for each gender at each work rate using Minitab® statistical software (Minitab, Inc., State College, PA).

RESULTS

The intent of the Anderson et al. study (forthcoming) was to collect data using subjects of both genders representing a wide range of age, as might be found in a workplace population. Physiologic responses relevant to this discussion are summarized in Table II.

Table II. Summary of Physiological Responses to Exercise

Variable (Units)	40% Work Rate Mean (S.D.)		60% Work Rate Mean (S.D.)		80% Work Rate Mean (S.D.)	
	Men	Women	Men	Women	Men	Women
$(V_I)(L/min)$	33.5 (5.8)	25.3 (2.4)	54.1 (12.6)	36.7 (5.8)	83.4 (21.2)	54.6 (12.4)
$\overline{PIF}$ (L/min)	104.8 (22.0)	93.2 (11.0)	164.4 (37.7)	127.2 (15.1)	243.3 (50.2)	178.5 (31.7)
PIF_{max} (L/min)	127.8 (30.4)	122.0 (30.4)	201.9 (35.2)	158.7 (23.2)	281.6 (50.5)	211.7 (42.4)
Individual PIF_{max}	183.2	172.4	272.6	191.1	387.0	257.7
F (breaths/min)	20.6 (5.3)	23.8 (5.1)	24.8 (7.1)	29.1 (5.7)	30.9 (8.0)	33.5 (6.9)
$\overline{V}_t$ (L)	1.68 (0.32)	1.09 (0.18)	2.23 (0.26)	1.27 (0.11)	2.71 (0.21)	1.64 (0.16)
$\overline{T}_I$ (sec)	1.41 (0.39)	1.05 (0.21)	1.21 (0.37)	0.88 (0.17)	0.96 (0.24)	0.79 (0.15)
$\overline{T}_{tot}$ (sec)	3.09 (0.78)	2.57 (0.50)	2.59 (0.71)	2.11 (0.42)	2.05 (0.51)	1.97 (0.46)
DC	0.46 (0.02)	0.41 (0.02)	0.46 (0.02)	0.42 (0.02)	0.47 (0.01)	0.43 (0.02)
$\overline{HR}$	98.2 (11.7)	101.1 (7.2)	122.4 (15.4.0)	119.9 (10.7)	151.3 (17.3)	144.8 (13.5)
Individual HR_{max}	116	109	145	132	180	164

It is important to note that the V_I , $\overline{PIF}$ and PIF_{max} measurements demonstrate increased variability with increased work rate. The no resistance values of Silverman et al. (1943), which are most similar to the present study, were analyzed for similar trends. As expected, V_I and "maximum flow," i.e.,

the $\overline{PIF}$ of 6-10 breaths, followed the same pattern of increased variability with increasing work rate. This must be taken into account in any discussion of appropriate airflow rates for respirator testing. The distributions of V_I and PIF_{max} values for the men and women in the study, as shown in Tables III and IV must also be considered. It is interesting to note that the 50th percentile V_I value for men at the high work rate in this study closely approximates the 85 L/min continuous airflow rates used in U.S. filter penetration testing (CFR, 1995). The adequacy of this flow rate will be discussed later in this paper.

Table IIIa. Distribution of Minute Volume Data-Male Subjects (L/min)

Work Rate	5 th Percentile	50 th Percentile	95 th Percentile
40%	24	33	43
60%	33	54	75
80%	49	83	118

Table IIIb. Distribution of Minute Volume Data-Female Subjects (L/min)

Work Rate	5 th Percentile	50 th Percentile	95 th Percentile
40%	21	25	29
60%	27	37	46
80%	34	54	75

Table IVa. Distribution of PIF max Data- Male Subjects (L/min)

Work Rate	5 th Percentile	50 th Percentile	95 th Percentile
40%	78	128	178
60%	144	202	260
80%	199	282	365

Table IVb. Distribution of PIF max Data- Female Subjects (L/min)

Work Rate	5 th Percentile	50 th Percentile	95 th Percentile
40%	72	122	172
60%	121	156	197
80%	142	212	281

Estimation of PIF_{max}

In addition to discussion of volumetric flow rates for respirator testing, Caretti et al., (2004) suggested that "... testing should mimic real world use as much as possible. Our recommendation would be to test PIF impacts under cyclic flow conditions as would be observed during human breathing to gain a truer understanding of respirator or filter performance under extreme flow conditions". It has also been suggested that PIF_{max} flow rates may adversely affect the performance of respirator filters and cartridges (Caretti et al., 2004; Kaufman and Hastings, 2005). Knowledge of the shape of the respiration waveform and expected PIF_{max} values during work activities would be necessary for cyclic flow tests. Because minute ventilation is easier to measure in work environments than peak flow rates, much more ventilation data is available in the literature.

Because of this, several simple methods have been suggested to allow PIF_{max} to be estimated from V_I measurements. It has generally been assumed that a sinusoidal waveform adequately represents

the breathing pattern (Cooper, 1960). If this were true, the $\frac{PIF_{max}}{V_I}$ ratio would equal π or approximately

3.14. Silverman et al. (1943) calculated $\frac{PIF_{max}}{V_I}$ ratios from measurements made at inhalation

resistances of 0, 25 mm, 50 mm, 76 mm, 102 mm, 152 mm, and 203 mm of water (all measured at 85 L/min) and work rates including light (29 W), moderate (68 W) and heavy (102 W). They also recommended average values to be used to estimate PIF_{max} from V_I for conditions ranging from

sedentary through maximum exertion. It was found that the $\frac{PIF_{max}}{V_I}$ ratios were lowered by increases in

work rate and by inhalation resistance, i.e., the inhalation curve flattened slightly. Much more recently,

Kaufman and Hastings (2005) reported ratios of $\frac{PIF_{max}}{V_I}$ and $\frac{\overline{PIF}}{V_I}$ in a study of young U.S. Marines

wearing a military gas mask and chemical protective clothing. Inspiratory air flow was measured continuously with a turbine flowmeter while the subjects performed a range of tasks ranging from light/moderate work to heavy exertion.

Table Va summarizes the ratios obtained by Anderson et al. along with those of Silverman et al. and Kaufman and Hastings. In principle, Anderson's values should generally correspond to the Silverman no added inhalation resistance (NR) values and Kaufman and Hastings' measurements should correspond with Silverman's recommended moderate inhalation resistance (MR) values. It must be noted that the work rate classifications for the three studies are generally similar but not identical.

The $\frac{PIF_{max}}{V_I}$ ratios for the men in Anderson's study are slightly higher than Silverman's NR

measurements. The ratios for women are higher still, but in both cases the differences decrease with

increasing work rate. At the moderate work rate, Kaufman and Hastings' $\frac{PIF_{max}}{V_I}$ ratio is much higher

than Silverman's MR recommendation, and higher than any of the NR ratios for that work rate. This may

be anomalous because, as noted earlier, inhalation resistance normally reduces the $\frac{PIF_{max}}{V_I}$ ratio.

Kaufman and Hastings' value for heavy work is comparable to the NR ratios for both this study and Silverman's.

Further analysis of PIF_{max} data suggests that its use, and use of $\frac{PIF_{max}}{V_I}$ ratios overstate the

practical breathing requirements of individuals, particularly at high work rates. This is because, as noted

earlier, variability in V_I , $\overline{PIF}$ and PIF_{max} measurements increases with increasing work rate (Table II).

The data collected by Anderson et al. allowed the frequency of occurrence of individual flow rates to be

quantified for each measurement period. Additionally, because the sampling rate was 100 Hz, the

duration of each peak flow rate is, by definition, 0.01 second (10 ms). The histograms in Figures 1 and 2

show the frequency distributions of PIF_{max} measurements for the male and female subjects from this

study with the highest PIF_{max} values for their genders at the 80% work rate. The figures represent the

PIF_{max} values from 79 breaths for the man and 82 breaths for the woman. The maximum peak values of

387 and 258 L/min for the man and woman, respectively, occurred only once. Thus, it would be

unreasonable to base any respirator test requirement on PIF_{max} values, since they occur so infrequently.

As shown in Figures 1 and 2, both the mode and the mean of the measurements are much more

meaningful indicators of an individual's peak inhalation rates since they occur far more frequently than the

maximum peak. The ratios of $\overline{PIF}$ to V_I in Table Vb suggest that, in the context of respirator performance requirements, PIF_{max} is reasonably estimated by multiplying V_I measurements by π . That is, the sinusoidal waveform can be assumed. This is a reasonable and conservative approach for high work rate testing, since the respiratory waveform is known to assume a more rectangular or trapezoidal shape at higher work rates (Silverman et al., 1943, Lafortuna et al., 1984, Kaufman and Hastings, 2004). No data suggests that further precision is necessary or beneficial when cyclic flow is used for testing respirators or their components.

Table Va. Ratio of Maximum Peak Inhalation Flow to Minute Volume

Work Rate	Men			Women			Kaufman and Hastings ^a			Silverman	
	Mean (SD)	Min	Max	Mean (SD)	Min	Max	Mean (SD)	Min	Max	NR ^b	MR ^c
Light	3.8 (0.5)	2.9	4.5	4.8 (0.9)	3.9	6.4	---	---	---	3.3	3.0
Moderate	3.8 (0.5)	3.2	4.7	4.2 (0.4)	3.7	5.6	7.4 (2.26)	4.7	14.7	3.0	2.7
Heavy	3.5 (0.5)	3.0	4.3	3.9 (0.3)	3.6	4.4	3.1 (0.63)	2.8	5.9	2.8	2.6

^a52 mm water inhalation resistance @ 82 L/min

^bMean of values measured without added resistance

^cValues recommended for devices with moderate (25-76 mm water) inhalation resistance

Table Vb. Ratio of Mean Peak Inhalation Flow to Minute Volume

Work Rate	Men			Women			Kaufman and Hastings ^a		
	Mean (SD)	Min	Max	Mean (SD)	Min	Max	Mean (SD)	Min	Max
Light	3.1 (0.3)	2.7	3.5	3.7 (0.44)	3.2	4.4	---	---	---
Moderate	3.0 (0.2)	2.8	3.3	3.5 (0.3)	3.2	3.8	3.5 (0.89)	2.5	7.3
Heavy	3.0 (0.2)	2.7	3.4	3.3 (0.25)	3.2	3.8	2.5 (0.39)	1.9	3.6

^a52 mm water inhalation resistance @ 82 L/min

Duration of PIF_{max}

PIF_{max} values must also be described with regard to their duration when they are considered in setting respirator performance requirements. Figure 3a shows the two minutes of respiration data collected at 80% VO_2 max for the male subject with the highest PIF_{max} in the Anderson et al. study. These data were analyzed to locate the breath with the highest PIF_{max} , which is shown in Figure 3b. Results of the $V_{peak} \pm 5\%$, $V_{peak} \pm 10\%$, $V_{peak} \pm 25\%$ determinations for this breath are presented in Table VI. As shown, an extremely small volume of air is flowing at the PIF_{max} rate of 387 L/min. At the $\pm 25\%$ interval, more than half of the tidal volume (1.79 L) is inhaled at the mean flow rate of 346 L/min. For this reason, it is suggested that a useful definition of peak flow rate (if such a term were to be incorporated into respirator performance criteria) be the mean measured flow rate during the highest consecutive 50% of the inhalation cycle. Mean inhalation time at the highest work rate in the Anderson et al. study was 0.99 seconds for men and 0.83 seconds for women. Thus, use of the proposed definition would describe a reasonable time interval (approximately 0.50 sec using the male values of Anderson et al.) for "peak" flow during which a significant volume of air would be expected to challenge the respirator or component. This is also logical

from the inhalation exposure control perspective, since the dose of a toxic material received by individual is fundamentally defined by the contaminant concentration and exposure duration.

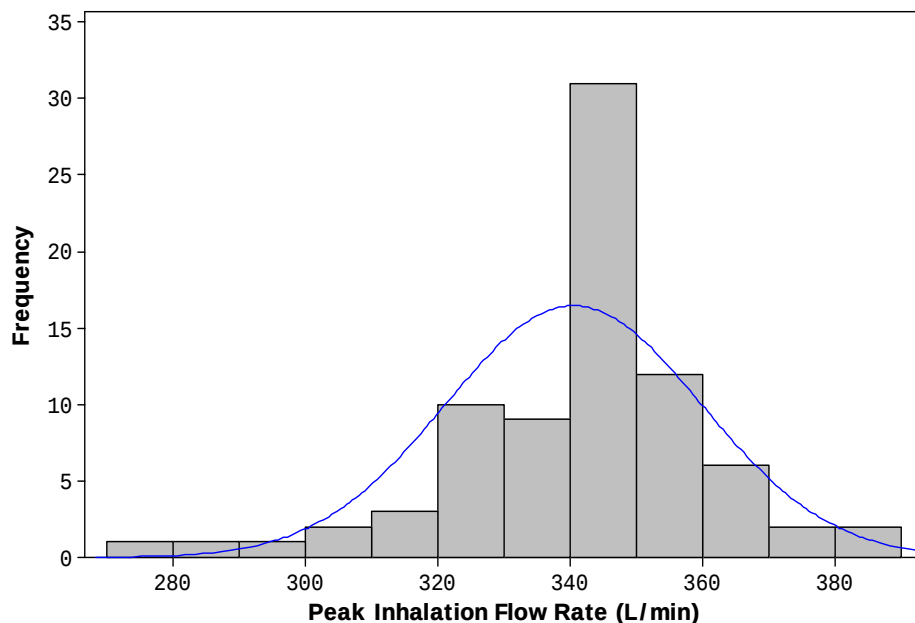


Figure 1. Frequency distribution of maximum peak flow rates, 80% work rate, male subject with highest PIF_{max} .

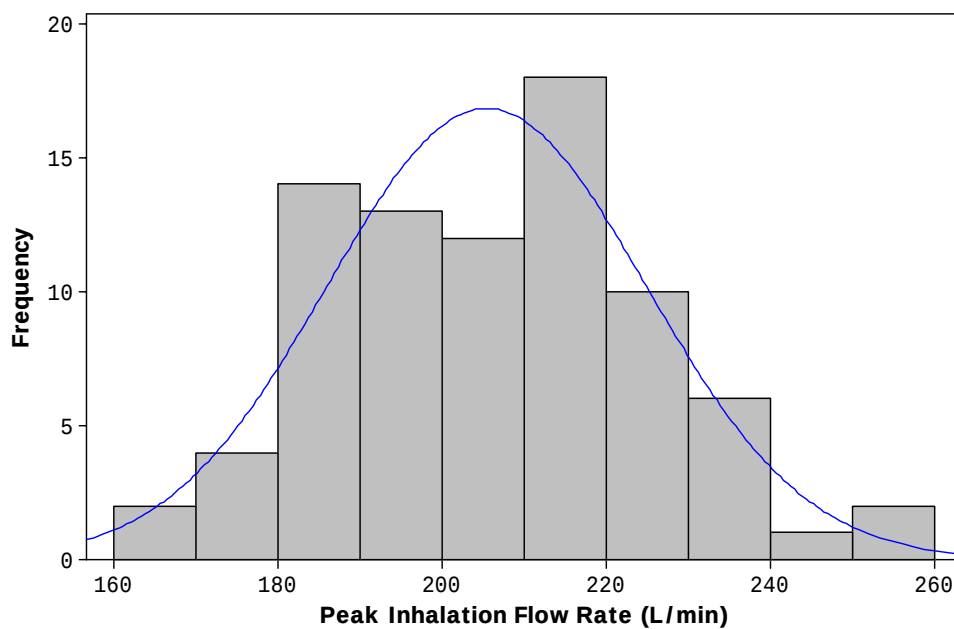
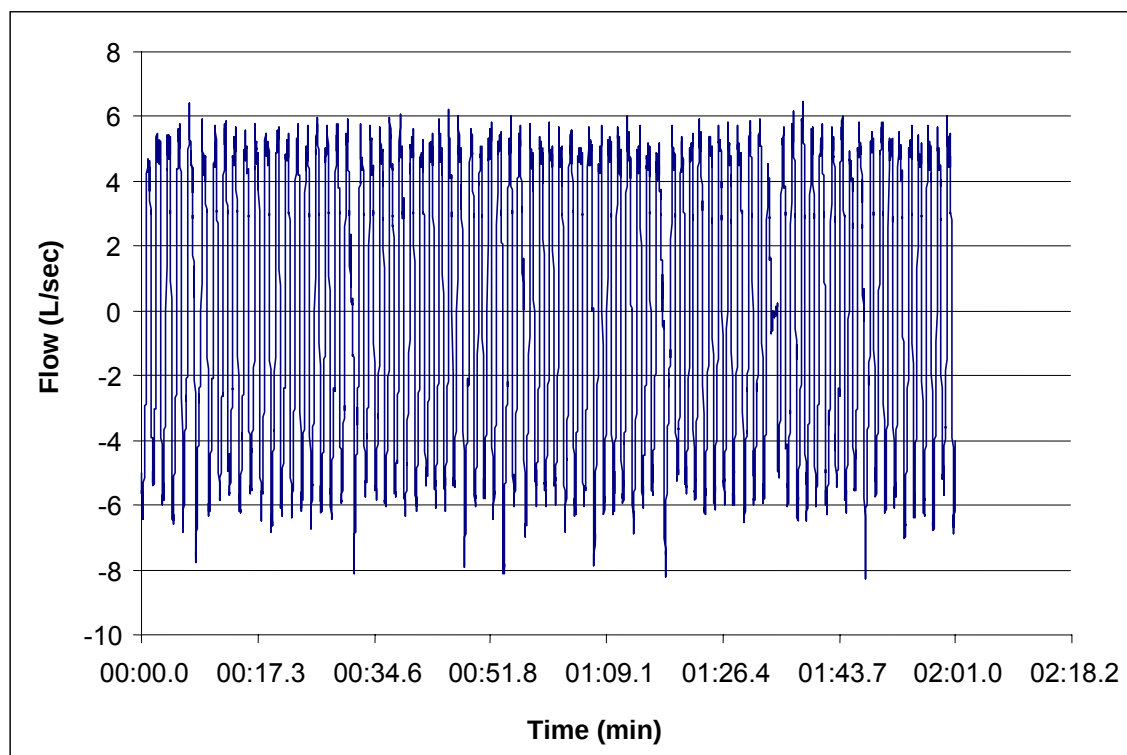


Figure 2. Frequency distribution of maximum peak flow rates, 80% work rate, female subject with highest PIF_{max} .

Table VI. Breath With Highest PIF_{max} at 80% VO_2 max

	Mean Rate (L/min)	Flow Duration (sec)	Volume (L)	% of Total Breath Volume
Maximum Peak	387	0.01	0.06	2.3
$V_{peak} \pm 5\%$	373	0.07	0.44	15.6
$V_{peak} \pm 10\%$	360	0.13	0.78	27.9
$V_{peak} \pm 25\%$	346	0.31	1.79	64.1
Total Inhalation	279	0.60	2.79	100
Total Breath Duration		1.36		

**Figure 3a. Breathing data for male subject with highest V_I and PIF_{max} at 80% VO_2 max.**

Performance of Currently Approved Respirators

Particle Filters

As noted earlier, there are no published reports of inadequate protection provided by currently approved respirators when they are properly selected, maintained and used. To the contrary, numerous workplace protection factor (WPF) studies have shown that respirators with filters tested at the flow rates specified in U. S. regulations 30 CFR 11 and 42 CFR 84 provide the expected level of protection when they are properly selected, worn and used (Myers and Zhuang 1998; Nelson, 1995; Bidwell and Janssen, 2004). WPF is a direct measurement of respirator performance capabilities in a specific work environment (AIHA, 2002). These data demonstrate that the flow rates and other performance criteria at which these

respirators were tested were adequate. Table VII summarizes the flow rates at which particle filtering respirators were tested under these regulations.

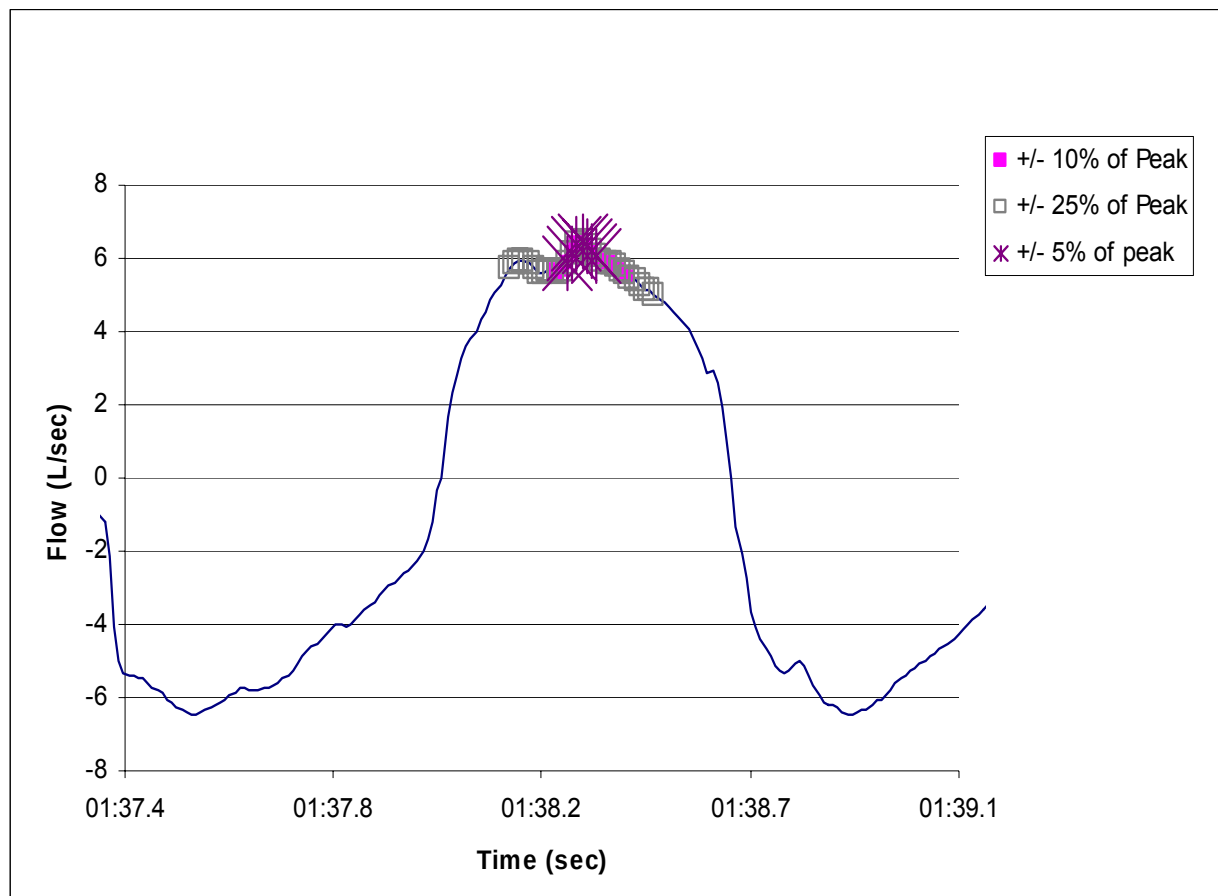


Figure 3b. Breath with highest PIF_{max} at 80% V_{O_2} max.

Table VII. Selected Filter Testing Conditions

	30 CFR Part 11		42 CFR Part 84
	Dust/Mist Filter	"HEPA" Filter	N Series
Particle Size, μm (CMD)	0.4	0.3	0.075
Particle Size, μm (MMAD)	1.7	Unknown ^a	0.24
GSD	2	Not specified	1.86
Airflow Rate	32 L/min continuous	32 and 85 L/min continuous	85 L/min continuous

^aBecause a GSD is not specified, MMAD cannot be calculated.

Adequate workplace performance of approved respirators is the expected outcome of any laboratory test, provided the respirators that pass the test are properly selected, maintained and used. It must be recognized that laboratory performance tests cannot predict the *protection* a respirator will provide in the workplace. The tests can only assess a particular performance parameter under specifically identified conditions. For example, laboratory tests can measure pressure drop characteristics, particle filter efficiency or carbon capacity for a particular vapor under specifically stated conditions of airflow, particle size and/or vapor concentration. Passing a laboratory test indicates a respirator or component is deemed suitable for use in certain workplace environments, which are presumed to be no more rigorous than the laboratory test conditions (Federal Register, 1995; Moyer and Stevens, 1989). Respirator use conditions differ from laboratory tests in contaminants/concentrations, particle size, temperature and relative humidity and breathing rates. Face seal characteristics vary among users and within each user over time (Krishnan et al, 1994; Myers et al, 1995, Nicas and Neuhaus, 2004). As a result, no laboratory test can predict the degree of protection a device will provide in actual use. At the same time, filters tested using dramatically different test conditions as listed in Table VII provided their expected level of workplace protection. This demonstrates that different laboratory tests can assure that the expectation stated earlier in this paragraph is met: an acceptable minimum level of workplace protection will be met or exceeded when approved respirators are properly selected, maintained and used.

Particle filter efficiency modeling is helpful to illustrate why the previous statement is true. A series of equations for estimating single-fiber filter efficiency are available in the literature (Hinds 1982). The interaction of the mechanical particle removal processes of impaction, interception, diffusion and gravitational settling are summed to predict overall single fiber filtration efficiency. This estimate can then be used to calculate the estimated overall efficiency of an entire filter with stated design characteristics.

Two hypothetical filters were modeled to examine the effect of airflow rate and particle size on particle filter performance. The first filter was “designed” to perform near the mean value of three brands of N95 filters (Janssen, 2004; Janssen and Bidwell, 2005) when subjected to the class N95 test specified in current U. S. regulations (CFR, 1995). The second filter was “designed” to perform near the 5% maximum penetration limit for the same test. The count and mass penetrations of each filter were then modeled using the 5735 inhalation flow rate data points of the male subject with the highest minute volume and peak flow rate in the Anderson et al. study (forthcoming) at 80% VO_2 max. The challenge aerosols used for the modeling exercise were a cement dust described previously (Janssen 2004) and a diesel particulate (Janssen and Bidwell, 2005). Challenge conditions assumed for the modeling are summarized in Table VIIIa. Count and mass penetrations were calculated at each inhalation flow rate and then frequency-weighted for an overall estimate of penetration for the inhalation portion of the exercise period. Results are presented in Table VIIIb.

Table VIIIb indicates that either of the modeled filters would be expected to perform very well against two aerosols typically found in workplaces. Most significantly, mass penetrations for both “real world” aerosols were *lower* than the penetration predicted under NIOSH test conditions, in spite of the high V_I and PIF_{max} values. Mass penetration is most significant because the occupational exposure limits for cement dust and diesel particulate (and nearly all other contaminants) are based on the mass of the contaminant inhaled (ACGIH, 2004). The modeled mass penetration estimates for the industrial aerosols are in general agreement with measured values from field studies using continuous flow rates equivalent to V_I of 50 to 60 L/min, e.g., 0.024% and 0.121% for two manufacturers’ N95 filters exposed to cement dust (Janssen, 2004). Additionally, diesel particulate penetration, measured as elemental carbon, averaged 1.2% and below the detection limit for R95 and P95 filters from different manufacturers (either of which might be used for diesel particulate exposures), respectively (Janssen and Bidwell, 2005).

It must be emphasized that these modeled penetration values are approximations for the inhalation portion of the respiration cycle only. Because inhalation was approximately 47% of the respiration cycle (i.e., $\text{DC}=0.47$) at 80% VO_2 max for the men in the Anderson et al. study, the weighted average penetration for the exercise period would be slightly less than half that predicted by the model. In addition, the high airflow rates associated with the 80% VO_2 max work rate can only be sustained for approximately 15 minutes in average individuals (Lumb, 2000; Sharkey and Gaskill, 2001). It is therefore

evident that filter penetration averaged over a longer work period would be much lower than the predicted values.

Given both the measured and modeled performance of these class 95 filters, it is unlikely that filters with higher levels of laboratory efficiency (or subjected to more severe laboratory testing) would increase worker protection. Total penetration for half and full facepiece respirators is generally assumed to be 10% and 2% (corresponding to assigned protection factors of 10 and 50), respectively (CFR, 2001a; CFR, 2001b) when they are properly fitted and used. Workplace data indicate that most of this penetration enters during momentary interruption of the facepiece to face seal (Myers et al, 1995). The contribution of penetration through existing filters is extremely small relative to total expected penetration. Nonetheless, filters with higher laboratory efficiency are available for users who believe they are necessary, e.g., class 100 filters must have less than 0.03% penetration under NIOSH test conditions. There are no data in the literature that suggest the NIOSH 85 L/min continuous airflow rate needs to be changed to assure acceptable filter performance.

Table VIIa. Challenge Conditions for Filter Penetration Estimates

	NIOSH Challenge	Cement Dust Challenge	Diesel Particulate Challenge
Particle Size, μm (CMD)	0.075	0.027	0.0023
Particle Size, μm (MMAD)	0.24	4.7	1.8
GSD	1.86	3.7	4.4
Airflow Rate	85 L/min continuous	Respiration Measurements $V_I = 119$ L/min $PIF_{\text{max}} = 387$ L/min	Respiration Measurements $V_I = 119$ L/min $PIF_{\text{max}} = 387$ L/min

CMD is count median diameter;
MMAD is mass median aerodynamic diameter;
GSD is geometric standard deviation.

Table VIIb. Filter Penetration Estimates

	NIOSH Challenge ^a	Cement Dust Challenge ^b	Diesel Particulate Challenge ^b
Count Penetration (%)			
Modeled Filter 1	0.38	1.07	0.25
Modeled Filter 2	3.74	5.05	1.28
Mass Penetration (%)			
Modeled Filter 1	0.42	0.05	0.31
Modeled Filter 2	4.31	0.33	1.32

^a Initial penetration estimate

^b Weighted mean penetration of initial penetration estimates during inhalation cycle, two minutes of exercise at 80% VO_2 max. Does not include decrease in penetration from filter loading.

Gas and Vapor Filters

Performance of gas and vapor filters (cartridges and canisters) has also been widely studied. Breakthrough time, i.e., the time required for a stated concentration of a contaminant to be detected downstream of the sorbent bed, is known to decrease as volumetric flow increases. Thus, the expected V_I of potential users is one performance consideration for gas and vapor filters. Respirator approval requirements typically specify sorbent breakthrough time be measured using a challenge agent passed through the canister with continuous airflow (CEN, 2000b; CFR, 1995). When negative pressure respirators are in actual use, however, air flows through the sorbent only during inhalation, i.e., the airflow pattern is cyclic (intermittent). It is therefore important to know if breakthrough behavior is significantly affected by the pattern of airflow as well as the total air volume passed through the cartridge. Finally, it may be important to determine if air flowing through the cartridge at or near a user's PIF_{max} will remain in contact with the sorbent long enough for the contaminant to be removed. That is, sufficient bed residence time must be ensured.

In a thorough study of respirator cartridges, Nelson and Harder (1972) reported no significant difference in breakthrough times between continuous and cyclic flow patterns. In contrast, Suzin et al. (2000) and Linders et al. (2003) concluded that breakthrough time was shortened by a cyclic flow pattern, particularly when very low breakthrough concentrations were measured. Both of the latter investigators suggested that testing with gas filters with cyclic airflow would allow better prediction of service life than continuous airflow testing.

Because of major differences in their design (Table IX), the results of these three studies are difficult to compare. However, both Nelson and Harder and Suzin et al. tested actual respirator cartridges, so their studies are more easily related to respirator use. Nelson and Harder's was the most comprehensive of the three studies, in that a wide range of flow rates and seven solvents were evaluated. Their airflow rates represent V_I at conditions from rest to very heavy work (Silverman, 1943). Since these airflows were drawn through a single cartridge normally used in a pair, the face velocities listed would be those seen at V_I values of 28-142.8 L/min. Resulting bed residence times at the highest continuous flow rate used would be approximately 0.06 sec. Under cyclic flow conditions, the PIF_{max} was approximately 185 L/min (Nelson et al. 1972), resulting in a face velocity equivalent to a peak flow rate of 370 L/min inhaled through a pair of these cartridges. Bed residence times at this flow rate would have been approximately 0.03 sec.

It is important to note that the cartridges Nelson and Harder tested were smaller and contained less carbon than cartridges and canisters currently approved in the U.S. It is now common for a single cartridge from a NIOSH approved system to contain more than 100 cm³ of carbon and have a cross-sectional area greater than 45 cm² (Yoon et al., 1996; MSA, 2005). Because breakthrough time is positively affected by carbon volume and potentially negatively affected by velocity (shorter bed residence time) (Ackley, 1985; Wood and Moyer, 1991) it is logical to expect today's cartridges and canisters to perform better than the cartridges Nelson and Harder tested. That is, breakthrough times and bed residence times would both be greater than Nelson and Harder found, given the same test conditions.

Since Nelson and Harder did not measure breakthrough concentrations below 1%, it is not possible to determine if they would have seen the differences between cyclic and continuous airflow at the low breakthrough concentrations studied by Linders et al. or Suzin et al. The latter study reported that cyclic flow shortened canister breakthrough time by about 5%, with coefficients of variation ranging from approximately 1.3 to 5.1%. Linders et al. found that the difference between cyclic and continuous flow breakthrough times became smaller at higher breakthrough concentrations. For example, with a 1.5 cm bed depth, the difference in breakthrough time was 35% at 0.1% breakthrough, progressively decreasing to 23% at 1% breakthrough and approximately 5% at 10% breakthrough. They did not report the variability of their measurements. At 1% breakthrough Nelson and Harder (1972) recorded differences on the order of 2%-9% at some flow rates, but noted that this variation was smaller than the variability measured within cartridges of the same type.

The significance of breakthrough concentrations in the 0.0016%-0.1% range used by Linders et al. and Suzin et al. is subject to debate. The logic for these criteria is that military agents may be toxic at extremely low concentrations, so a very small amount of penetration through a canister is cause for concern. As noted earlier in this paper, the APF of 50 for full facepiece negative pressure respirators

indicates that 2% overall penetration is expected from the device. Also as stated earlier, most of the penetration for any negative pressure respirator likely results from momentary interruptions in the facepiece-to-face seal (Myers et al, 1995). While it is not common for military organizations to use APFs for respirators worn by soldiers, no data has been published to suggest their face seal characteristics in actual use would be different than those of civilian respirators. To the contrary, very similar performance was reported in a small study of simulated workplace protection factors (SWPFs) during military field trials (van der Gijp and Steenweg, 2004). SWPF is a measure of respirator performance that is done in a laboratory setting using test exercises designed to simulate work (AIHA, 2002). The authors found average SWPFs ranging from approximately 200 to more than 6000 over five tasks performed by two experienced (but not fit tested) respirator users. These results suggest that the face seals of military respirators perform in much the same way as civilian devices during actual use.

Table IX. Selected Study Characteristics

	Nelson and Harder	Linders et al.	Suzin et al.
Element tested	Two brands of commercially available cartridges	Glass tube surrogate for canister	Commercially available canister
Carbon	8-16 and 12-20 mesh granules	1 mm x 3-5 mm extrudates	20 x 30 mesh impregnated carbon
Carbon volume	72 and 80 cm ³ at max density	19.6-68.6 cm ³ (estimated)	152 cm ³ (estimated)
Bed depth	2.3 and 2.1 cm	Varied from 1-3.5 cm	1.7-1.8 cm
Diameter	6.3 and 7.0 cm	5 cm	10.5 cm
Bed cross-sectional area	31.2 and 38.5 cm ²	19.6 cm ²	86.6 cm ²
Flow rate	14, 20.6, 29.8, 36.9, 53.3, 71.4 L/min continuous and cyclic flow	15 L/min continuous and cyclic flow	30 L/min and 45 L/min continuous and cyclic flow
Face velocity	7.5-38.1 cm/sec and 6.1-30.9 cm/sec for continuous flow 35.3-98.8 cm/sec and 28.6-80.1 cm/sec max for cyclic flow (estimated)	12.8 cm/sec for continuous flow 40 cm/sec max for cyclic flow	5.8 and 8.7 cm/sec for continuous flow 18.1 and 27.2 cm/sec max for continuous flow
Challenge agent	Toluene, ethyl acetate, trichloroethylene, cyclohexane, methyl chloroform, butyl alcohol, 2-butanone	Toluene	Dimethyl methyl phosphonate
Challenge concentration	1000 ppm	1274-2654 ppm	3000 mg/m ³
Breakthrough times reported	1%, 10%, 50%, 99%	0.01%, 0.1%, 1%, 10%, 100%	0.0016%

The reality of face seal leakage must be taken into account when a negative pressure respirator is selected for use in an extremely hazardous environment. It can be argued that the initial very low breakthrough concentrations ($\leq 0.1\%$) are not significant, since the face seal leakage is likely to be more than an order of magnitude higher. Once again it must be emphasized that no laboratory test can predict

protection or breakthrough time in actual use. This is because of variability in exposure concentrations, environmental conditions, breathing rates and faceseal characteristics among users.

Based on the three studies discussed above, cyclic flow testing appears to result in a small reduction in breakthrough time for some chemicals at very low breakthrough concentrations. Additional studies should be conducted to confirm or refute these findings and to determine their significance to respirator users. Aside from assuring a minimum carbon capacity, neither cyclic nor continuous flow laboratory tests can predict when a user might experience breakthrough. Thus, there is no benefit to changing to cyclic flow testing on the theory that it will better predict when breakthrough will occur. Because cartridges and canisters in today's respirators have larger bed volumes than those tested by Nelson and Harder, it is unlikely that residence times for respirators in actual use would be less than in their study. That is, breakthrough because of insufficient bed residence is extremely unlikely. Again, further studies should be done to verify or disprove this observation. Similar work with inorganic gases should also be conducted. However, at this time, there is no evidence that changing to cyclic flow testing or higher flow rates would benefit users of cartridge and canister style respirators by providing better protection.

Positive Pressure Respirators

Powered air purifying respirators (PAPR), continuous flow and pressure demand supplied air respirators (SAR), and pressure demand self-contained breathing apparatus (SCBA) are by design intended to maintain a slightly greater than ambient pressure in the inlet covering (facepiece, hood or helmet) during both inhalation and exhalation. Because contaminants are unlikely to migrate from ambient pressure to a higher pressure, positive pressure respirators have been assumed to provide more protection than negative pressure respirators. In principle, a positive pressure respirator can be momentarily drawn into negative pressure (overbreathed) if the wearer's PIF_{max} exceeds the device's airflow delivery plus the dead volume of the inlet covering.

Performance considerations for tight-fitting respirators: Numerous reports of overbreathing tight-fitting positive pressure respirators exist in the literature (Myhre et al., 1979; Dahlback and Novak, 1983; Wilson et al., 1989). These reports involved respirators designed and approved in the 1970's and early 1980's. Partly as a result of these reports, higher airflow performance criteria were adopted for SCBA used in firefighting (NFPA, 2002). These criteria require a minute volume of at least 103 ± 3 L/min with a peak flow capability in excess of 300 L/min. Even with these airflow capabilities, at least two studies have reported negative pressure excursions in the facepiece at high work rates (Campbell et al., 1994, Burgess and Crutchfield, 1995).

Campbell et al. (1994) collected data on pressure inside the facepiece of SCBA during actual fire fighting activities. They used this information along with a sophisticated mathematical model to estimate the effect of overbreathing on the protection provided by the SCBA. Their model takes into account the duration and frequency of overbreathing, protection expected when positive pressure is maintained as well as when overbreathing occurs, and additional factors. The authors concluded that the effect of overbreathing is not significant and recommended that the assigned protection factor (APF) remain at 10,000.

A much simpler approach using information from Burgess and Crutchfield (1995) supports this conclusion. In their study, firefighters wearing SCBA exercised on a treadmill at 80% of their aerobic capacity. It must be emphasized that this is a work rate that most individuals could not sustain for more than approximately 15 minutes at a time. Facepiece pressure was monitored and V_I was determined for each subject. The authors found that in the worst case a subject experienced negative pressure in the facepiece 5.75% of the time. Because SCBA facepieces must demonstrate a faceseal penetration of 0.2% or less in the negative pressure mode in the U.S. (CFR 1998), it is reasonable to assume this leak rate during negative pressure excursions. The faceseal penetration of 0.2% is applied during overbreathing and the overall expected penetration for pressure demand SCBA (0.01%) is used when positive pressure is maintained. Because respirator efficiency in reducing exposure is equal to 100% minus % penetration, the overall efficiency of the device for the worst-case subject for the 15 minute period would be calculated as:

$$\text{Overall \% efficiency} = \frac{(5.75 \times 99.80) + (94.25 \times 99.99)}{100} = 99.98\%$$

Thus, it is easily seen that the occasional negative pressure excursions seen in tight-fitting positive pressure respirators have minimal effect on overall performance, even during periods of heavy work.

Performance considerations for loose-fitting respirators: The most comprehensive study of airflow rates, pressure in the inlet covering and simulated workplace performance factors (SWPF) of loose fitting respirators was published by Cohen et al. (2001). Negative pressure excursions were found with all the hooded loose-fitting facepiece PAPR and SAR tested, most often when the subjects ran in place. The authors found no consistent relationship between the pressure measurements and the SWPF measurements. Mean airflow rates were above the required six CFM for all the devices, but flow rates as low as 4.66 and 5.27 CFM were found for one hooded and one loose-fitting facepiece PAPR, respectively. Both of these devices were from the same manufacturer and used the same blower, filters and battery pack. Interestingly, the 5th percentile SWPF measurements remained at or above 150,000 for both devices, and the configuration with the lower airflow had the higher 5th percentile SWPF (>250,000 vs. 150,000-230,000) of the two devices. This is likely because the higher performing device used a full hood while the lower performing device had a loose-fitting facepiece. That is, they had different design characteristics that affected their protective performance to a greater extent than their rate of airflow.

Fifth percentile SWPF values ranged from 86,000 to more than 250,000 for all but one of the remaining devices. The SAR with the highest mean and minimum airflows did not have the highest measured SWPFs, and the poorest performing device did not have the lowest mean or minimum airflow. This demonstrates that increased airflow does not assure a higher level of performance. In fact, the poorest performing SAR (5th percentile SWPF 13-18) was identical to another device from the same manufacturer, except the poorest performer lacked a bib. Airflow for the two devices was virtually identical, yet the device with the bib had 5th percentile SWPF of 150,000-240,000. The results of this study indicate that:

1. The effect of occasional negative pressure spikes on the protection provided by loose-fitting respirators is not great;
2. Design characteristics other than air flow rate can dramatically influence the performance of loose-fitting respirators; and
3. Higher airflow rates do not assure better performance.

Finally, it should be noted that recent WPF studies on loose-fitting facepiece PAPR and SAR with hoods or helmets support the current APFs of 25 and 1000, respectively (Colton and Bidwell, 2001; Nelson et al., 2001).

In summary, the current airflow requirements for both tight and loose-fitting positive pressure respirators appear to assure appropriate levels of respiratory protection when other factors such as configuration and fit are also properly addressed.

CONCLUSIONS

While it may seem intuitive to believe that respirators and their components should be tested at flow rates that closely match V_i and PIF_{max} values of expected users, that belief is not supported by objective data. Increased flow does not increase penetration of significant workplace particles through filters. The data reviewed indicate bed residence times for gas and vapor filters are adequate, but confirmation studies are needed. High workrates are not sustained for long enough periods of time to significantly reduce filter life due to rapid loading. Finally, the data indicate that overbreathing positive pressure respirators, if it occurs in a workplace setting, is extremely unlikely to significantly increase a respirator wearer's contaminant exposure.

Thus, existing data indicate that it is not necessary to use flow rates that approach PIF_{max} or maximum V_i rates of all users to assure respirators provide adequate protection. Airflow requirements of respirator users are appropriately taken into account in the current design and testing of respiratory protective devices. Other respirator design characteristics, combined with the differences between

laboratory test conditions and actual exposures, assure that users are adequately protected when the respirators are properly worn and used.

At this time there is no evidence that increasing airflow rates for testing filters or changing from continuous airflow to cyclic flow testing would increase wearer protection. The same can be said for air delivery requirements for PAPR, SAR and SCBA. Based on the best available information, existing respirators from all categories evaluated provide their expected levels of protection if they 1) meet current U.S. or other equivalent performance criteria, and 2) are properly used in conditions for which they have been approved. That is, there appears to be a sufficient margin of safety already built in to respirator approval tests.

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