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How Protective Are Respirator Assigned Protection Factors: An Uncertainty Analysis

This investigation evaluated the risk of overexposure for a selected assigned protection factor by performing Monte Carlo simulations. A model was constructed to assess respirator performance by calculating the concentration inside the respirator. Estimates of the factors that affect respirator performance were described as distributions. The distributions used a worst case estimate for concentration in the workplace, the worst case for respirator performance (the fifth percentile person), and the worst case for exhalation valve leakage. A Monte Carlo analysis then provided estimates of the percentage of time that concentration inside the respirator exceeded the occupational exposure limit (OEL). For a half-facepiece respirator with an APF of 10, the calculations indicated a low risk of being exposed above an OEL, with mean exposures being controlled well below an OEL.

Keywords: assigned protection factor, Monte Carlo analysis, respirator performance

For inhalation hazards, the airborne contaminant concentration is compared with the occupational exposure limit (OEL) to determine whether an exposure is excessive. OELs are intended to minimize health risks. They are set in a manner so nearly all workers may be repeatedly exposed at that concentration, day after day without adverse health effects.(1) When engineering controls and work practices to reduce exposures below the OEL are not feasible, respirators can be used to lower exposures.

In choosing a respirator to reduce a worker's exposure to a contaminant, various characteristics of the exposure and the respirator must be evaluated.(2) These characteristics include the hazard ratio (HR) and the assigned protection factor (APF).

The HR is defined as the measured or estimated exposure (EXP) divided by the OEL.(2)

$$\mathrm{HR} = \mathrm{EXP}/\mathrm{OEL} \qquad (1)$$

The averaging period for both EXP and OEL must be the same; typically, an 8-hour time-weighted average (8 hour-TWA) or 15-min time weighted short-term exposure limit (15-min STEL). A respirator is selected based on whether the APF is greater than the HR.

The APF is operationally defined as the minimum expected workplace level of respiratory protection that would be provided by a properly functioning respirator or class of respirators, to a stated percentage of properly fitted and trained users.(3) The percentage of users is not stated.

Several investigators have measured workplace protection factors (WPFs) provided by respirators. These WPFs are actual measured ratios of EXP/concentration inside (C_i) the respirator. The National Institute for Occupational Safety and Health and its investigators have used the point estimate of the fifth percentile of WPF data to set the APF for a number of respirator types.(4,5)

The American National Standards Institute (ANSI) Z88.2 (1992) standard does not specify the limiting percentage of users for setting APFs.(2) In setting APFs, the ANSI committee analyzed WPF studies and used the fifth percentile as a comparison point.(6) If the fifth percentile WPFs exceeded the previously established APFs, the APFs were judged acceptable. If not, a number was chosen that was lower than the fifth percentile estimates from the studies. For example, fifth percentile WPF estimates of 32, 41, and 27 for loose-fitting facepiece powered air-purifying respirators became an APF of 25.

An individual's respirator performance can vary from day to day, so it has been suggested that a fifth percentile estimate from a population of users may not be protective.(7) This led to a recommendation that the APF be based on inter- and intraperson variability.

When a respirator is selected with an APF greater than the HR, it is assumed the exposure inside the respirator will then be less than the exposure limit. None of the approaches for assigning protection factors used in the past have been evaluated and shown to maintain exposures below the exposure limit during all respirator use. The risk of overexposure while using a respirator with an APF set by the various methods is not known.

The purpose of this investigation was to evaluate the risk of overexposure for a selected APF by performing Monte Carlo simulations. A model using probability density functions for respirator performance and exposure as random variables was developed. A half-facepiece respirator was used as the specific type of respirator modeled. The study showed that a judgment can be made whether an APF of 10 for a half-facepiece is appropriate.

BACKGROUND

To evaluate the risk of overexposure, the concentration inside the respirator can be compared with the OEL. The concentration inside the respirator (C_i) is equal to the concentration in the workplace (C_o) times the fraction of leakage into the respirator.

$$C_i = C_o \times L \qquad (2)$$

where L = proportion leakage (dimensionless, 0.0 no leakage, 1.0 is total leakage).

Estimate of C_o

To estimate C_o several assumptions must be made. If a respirator is required, then it has been determined that the OEL is exceeded. There is no clear consensus on what is considered an acceptable statistical criteria for assessing compliance with an exposure limit. The Occupational Safety and Health Administration defines its permissible exposure levels as limits not to be exceeded.(8) A 5% probability of exceeding the exposure limit has been suggested and will be assumed for this simulation.(9)

If a respirator is required, it will be limited to concentrations that are less than the maximum use concentration (MUC). The MUC is the product of the exposure limit times the APF.

$$\text{MUC} = \text{OEL} \times \text{APF} \qquad (3)$$

The MUC also has the same averaging period as the OEL.

For a half-facepiece with an APF of 10 this limiting concentration is 10 times the exposure limit. The same criteria for exceedence of C_o without a respirator will be used for the MUC [i.e., a 5% probability that C_o will exceed (10)(OEL)] while the respirator is used.

Most air monitoring data is reasonably well described by the lognormal distribution.(10) The geometric mean of the concentration (GM_c) and geometric standard deviation (GSD_c) can be used to describe the data. For an individual workplace one can estimate the value of the GM_c and GSD_c from air monitoring data. But to assess respirator use in general, one needs to make some assumptions on the likely values of the GM_c and GSD_c.

Researchers have reported the GM_c and GSD_c for various industries.(11-18) For example, Buringh and Lanting reported on the variability of air monitoring data for 420 persons working in 25 industries in the Netherlands.(11) The mean GSD_c was 2.7 with most less than 5. Based on the data in the cited articles, a range of 2 to 6 for the GSD_c was chosen by the authors as an appropriate estimate of an individual's variation for exposures.

TABLE I. Calculated Values of the Geometric Mean of Airborne Concentration Based on a 5% Probability of Being Greater than an OEL of 10

GM[A]	GSD
3.2	2
1.6	3
1.0	4
0.7	5
0.5	6

[A] Calculated from: 95^{th} percentile = geometric mean × geometric standard deviation$^{1.645}$

Table I lists different lognormal distributions of workplace airborne concentrations with various GM_c and GSD_c combinations such that there is always a 5% probability of individual observations exceeding an arbitrarily chosen OEL of 10. GSDs of 2 to 6 represent the amount of variation likely to be found in a workplace. The GM_c is calculated based on a z value of 1.645 (or 1.645 standard deviations above the mean), which corresponds with the 95% point of the normal distribution.

When the geometric mean values listed in Table I are multiplied by 10, the resulting two parameter models describe the distributions of C_o at the MUC for a half-facepiece respirator. All of the distributions used in the analysis for C_o meet the criteria that no more than 5% of the time will the C_o value be greater than the MUC.

Estimation of Respirator Leakage (L)

An effective respirator program is intended to maximize the performance of a respirator by minimizing leakage. Leakage is defined by: L_{FS} = leakage through the faceseal; L_C = leakage through the cartridge or filter; L_D = leakage through a defect.

Leakage through the faceseal is affected by fit-testing, proper wearing, and training of respirator wearers. This model of respirator performance assumes that properly trained and motivated individuals wear the respirator. WPF data is used to estimate L_{FS}.

Table II lists the geometric mean of WPFs (GM_{WPF}), along with the geometric standard deviation (GSD_{WPF}) and number of samples collected for several studies. These studies were conducted with protocols that included fit-testing, proper wearing, and training of respirator wearers with respirators that were properly selected and maintained. The studies listed had individuals identified allowing individual GM_{WPF} WPFs and GSD_{WPF} s to be calculated.

Figure 1 shows GM_{WPF} versus the GSD_{WPF} for individuals with three or more WPF measurements for all of the studies listed in Table II (one outlier removed). A regression analysis showed an r^2 value of 0.15, which is statistically significant ($p = 0.001$). Though there is a weak relationship indicated between the GM_{WPF}

TABLE II. Summary of WPF Studies

Study	Industry	Number	GM	GSD
Dixon(25)	pigment manufacture	42	3360	4.8
Lenhart(26)	lead smelter	25	166	3.8
Nelson(27)	asbestos abatement	26	168	5.8
Gosselink(28)	brake manufacture	6	58	1.6
Colton(29)	pigment manufacture	58	469	3.6
Myers(30)	painting	36	3983	4.2
Colton(29)	ship breaking	47	205	3.5
Colton(12)	battery manufacture	44	315	3.3

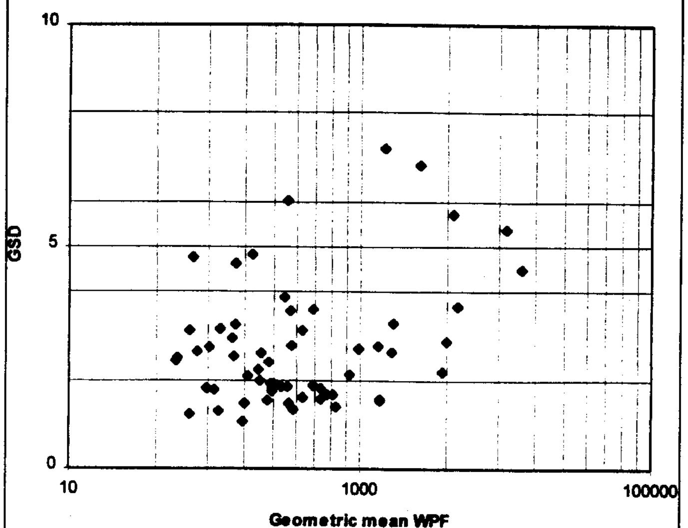

FIGURE 1. Geometric standard deviation (GSD) versus geometric mean workplace protection factor (WPF) for people with three or more measurements

and GSD_{WPF}, in the region of primary interest (WPFs <1000), the range of GSDs does not vary greatly with WPF. For this analysis, it is assumed that any person with a given GM_{WPF} respirator performance can have a GSD_{WPF} in the range found. Ninety-five percent of the GSDs calculated from this data range from 1.2 to 5. Values of 1.5, 2.5, 3.5, 4.5, and 5.5 were used to estimate respirator performance (R_{PF}) in the simulations.

The data listed in Table II has a GM_{WPF} mean of 540. The best estimate of the fifth percentile is 26. The variation was factored into person-person and within-person components through an analysis of variance, and the GM_{WPF} for fifth percentile person was calculated to be 44. This geometric mean was used for the estimate of R^{PF} in the simulations.

Leakage through the cartridge or filter is controlled by proper selection and appropriate replacement schedules. In modeling respirator performance it is assumed that the proper filter or cartridge has been selected. Filters may not be 100% efficient, and may allow small amounts of a material to leak into the respirator. If filter penetration occurs, it is accounted for in WPF measurements.

Leakage into the respirator can occur through defective or improperly installed cartridges, filters, and exhalation valves. Leakage through improperly installed or damaged cartridges or filters is assumed to be nil. Respiratory protection programs are required to include respirator inspection, maintenance, and storage procedures that prevent occurrence of leakage by these routes.

Brueck measured the leakage through new respirator valves.(19) For four of five respirators tested, the leakage was shown to be less than 10 cm^3/min. The fifth respirator had a measured leak rate of up to 100 cm^3/min. Assuming a light to moderate work rate, with an inhalation rate of 20 L/min, a leak rate of 100 cm^3/min would equate to a penetration of ~0.3%. Gee reported that a leak check of new respirators showed that 1% had a leak rate greater than 0.03%.(20) Most WPF studies are conducted on new or well-maintained respirators, so this minor amount of leakage is already contained in the measurement of the WPF.

Higher exhalation valve leakage could occur as the result of dirt accumulation on the valve after use. Exhalation valve leakage was determined for respirators used in a dusty environment and in a chemical industry.(19) The respirators had minimal leakage; 90% had a leak rate of less than 32 cm^3/min, 95% had a leak rate of less than 64 cm^3/min. One respirator (of 67) had a leak rate approaching 250 cm^3/min. Table III lists the frequency of the reported leak rates shown as penetration, assuming a 20 L/min flow through the respirator based on the above data. The highest value for the leak rate was used in the simulation as a conservative estimate of exhalation valve leakage.

TABLE III. Frequency of Leak Rates

Leak Rate (cm/m^3)	Fractional Leak Rate	Frequency
0–<32	0–0.0016	0.90
32–<64	0.0016–0.0032	0.05
64–<250	0.0032–<0.0125	0.04
250	0.0125	0.01

Estimation of the Concentration Inside the Respirator (C_i)

The concentration of the contaminant inside the respirator is a product of the concentration outside the respirator times the leak rate or total inward leakage. The leak rate is the result of the leakage sources—respirator leakage (estimated from WPF data) or leakage through the valves or other defects. This can be shown as:

$$C_i = C_o \times 1/(R_{PF}) + C_0 \times L_D \qquad \textbf{(4)}$$

where C_i is the concentration of the contaminant inside the respirator

C_o is the contaminant concentration in the workplace

$1/(R_{PF})$ is the estimate of respirator leakage

L_D is the estimate of defect leakage exceeding that for new respirators.

Table IV lists the values for C_o, R_{PF}, and L_D used in the simulation.

METHODS

Monte Carlo Simulation

A Monte Carlo analysis was conducted to estimate the level of protection being provided by half-facepiece respirators. This is a computer-aided stochastic (i.e., random, involving chance) probability analysis that allows one to more readily and completely process and present information and predictions provided by models and the uncertainty associated with these model predictions. In these analyses, the algorithm in Equation 4 was used. The ordinary use of this equation is to insert single values (perhaps worst case estimates) for each of the independent or predictor variables to obtain a single estimate of the dependent variable, C_i. The

TABLE IV. Summary of Parameters Used in the Simulation

C_o		R_{PF}		L_D^{A}	
GM	GSD	GM	GSD	Frequency	Rate
32	2	44	1.5	0.90	0.0016
16	3	44	2.5	0.05	0.0032
10	4	44	3.5	0.01	0.0125
7	5	44	4.5		
5	6	44	5.5		

[A] L_D was applied as the frequency listed for the 25 combinations of C_o and R_{PF}

Monte Carlo technique allows examination of the effect of inserting distributions for each of these predictor variables (C_o, $1/R_{PF}$, L_D) rather than point estimates of the best, worst, or averages of each.

Many people are used to thinking in terms of using single values for analysis and prediction. They are not accustomed to viewing variables in terms of distribution functions. It is important to realize that for the purposes of this analysis, the MUC is not a single value but a distribution of values. The MUC in this article is conceptually defined as a stochastic "condition" or probability density function. It is operationally defined as any distribution of airborne concentrations (within a range of GSDs from 2 to 6) that has 5% of its values above 10 times the OEL. The R_{PF} and the L_D are similarly defined.

For respirator use, there exists both inter- and intraperson variability.(7) The minimum respirator performance is represented in this analysis by the fifth percentile person, which is a GM_{WPF} estimated protection factor (R_{PF}) of 44 based on the data listed in Table II. Variability is described by the GSDs shown in Figure 1. Values of 1.5, 2.5, 3.5, 4.5, and 5.5 were used to estimate R_{PF}. Respirator exhalation valve leakage frequency (L_D) is shown in Table III and was used as the estimate for L_D for all simulations. Table IV lists the values for C_o, R_{PF}, and L_D used in the simulation.

The lognormal distributions for C_o, R_{PF}, and relative frequency distribution of L_D already described provide the input necessary to run a series of Monte Carlo simulations capable of predicting the composite risk to workers of overexposure while using a respirator.

A personal computer and readily available software (*Crystal Ball*(21) or *@Risk*,(22) which are available for an IBM-PC and compatibles as well as a Macintosh version) can be used to do this analysis. *Crystal Ball* was used for this simulation. This software automatically samples from each distribution of predictor variables. These values are constrained by the known or inferred parameters of the probability distribution function input for each predictor variable. The values in this sampling set of predictor variables are then put into the underlying algorithm (Equation 4), which produces a single prediction value for C_i.

Consider an example of a single sampling set of values for C_o, R_{PF}, and L_D. The greatest probability is that the value will be at the mode (or peak or most likely value) for each. This is because these have the greatest probability of occurring in the distribution. Values slightly higher and slightly lower than the mode in each distribution also have a relatively high, but slightly lower, probability of being sampled compared with the mode. Values in the distribution that are much lower or much higher than the mode have a much lower but still possible chance of being included in the sample. This randomly sampled set of single values (C_o, R_{PF}, L_D) is then put into Equation 4 and a single value of C_i is calculated.

This process is rapidly repeated for a large number (usually 10,000 or more) of independent "samples" and calculated predictions of C_i, which are accumulated in a corresponding distribution of predicted airborne concentrations inside the respirator, C_i. The resulting output is displayed as a forecast chart that shows the entire range of possible outcomes and the likelihood of achieving any of them.

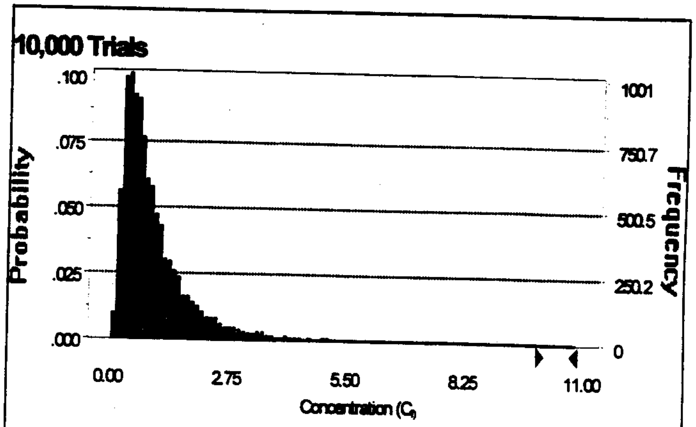

FIGURE 2. Frequency chart of concentration inside respirator, with a GM_{WPF} of 44, GSD_{WPF} of 1.5, GM_C of 32, and GSD_C of 2.0, with leak rates as in Table III

RESULTS

In this analysis all possible combinations of C_o, R_{PF}, and L_D, within the constraint of their assigned probability distributions, were collected into a distribution to estimate the percentage of C_i concentrations that were over the exposure limit. Each simulation set used 10,000 iterations. A typical run is shown in Figure 2 for a C_o concentration with a GM_c 32 (GSD_c of 2), respirator performance with a R_{PF} of 44 and a GSD of 1.5, and the exhalation valve leak rates shown in Table III. R_{PF} was constrained to values greater than 1 because only values greater than 1 can occur. In this case the Monte Carlo simulation predicts 0.07% of the exposures would be greater than the exposure limit of 10.

Calculations were run covering the described assumptions for C_o, R_{PF}, and L_D as listed in Table IV. This resulted in 25 simulation scenarios, 5 distributions of C_o, each with 5 distributions of R_{PF}. The results are shown in Figure 3. The highest percentage of time that C_i exceeds the OEL is 6.8%. This is considered a worst case estimate since not all workers use respirators at the maximum use concentration. The mean concentration found for each condition is shown in Figure 4. The highest mean concentration for C_i was 2.9 (compared with an OEL of 10).

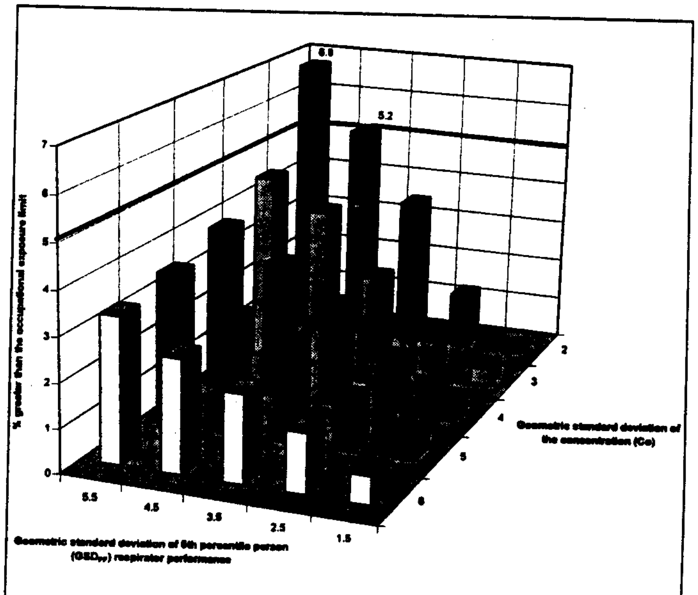

FIGURE 3. Percentage of time concentration inside the respirator is greater than the OEL

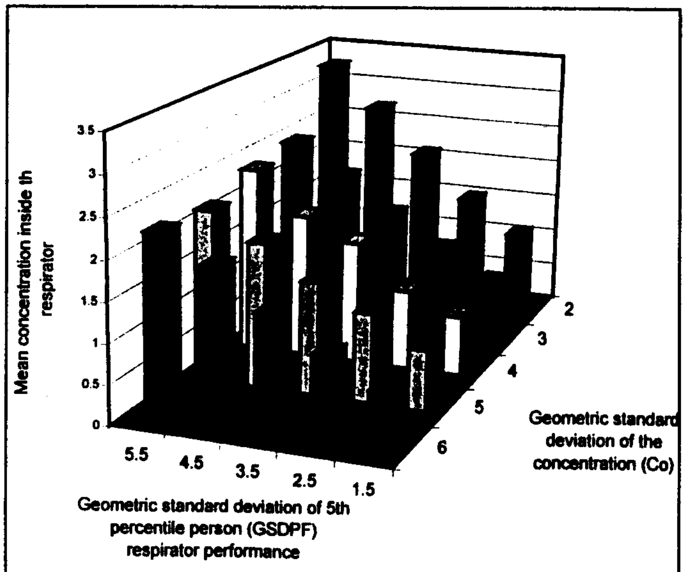

FIGURE 4. Mean concentration inside the respirator, with an OEL of 10

DISCUSSION

Hyatt set the first APFs.(23) These values were based on a laboratory quantitative fit-test. A panel of people were fit-tested with the available models of respirator. To assign a specific APF, 95% of the test panel had to pass the quantitative fit-test with that assigned value or higher on all of the facepieces tested. For example, in Hyatt's data from quarter-facepiece respirators equipped with high efficiency filters, greater than 95% of the panel achieved fit factors greater than 10 for 4 of 5 models tested. For the fifth model 94% achieved a fit factor greater than 10. This value was considered to be within acceptable experimental variation. Since 95% of the panel obtained >10 on all facepieces, 10 was assigned as the protection factor.

Myers suggested that WPF data be used as the basis for setting an APF for a respirator class.(5) He suggested that the APF for a given type of respirator could be based on the lower fifth percentile estimate of a WPF distribution or on a one-sided lower tolerance limit value above which the WPF values would be predicted to lie with a specific confidence level, such as 95%. Recently, Nicas proposed that a rigorous statistical procedure be used to evaluate WPF data to set the APF.(24)

Each of these approaches focuses on the performance of the respirator rather than the dose that a person may receive while wearing a respirator. Each also assumes that the respirator is always used at the MUC.

If single point estimates for exposure and respirator performance were used, very different estimates of exposure would be calculated. Consider a case in which the respirator is used at 100 (10 times the OEL of 10), with a GM protection factor of 44 and a GSD of 3.5. The fifth percentile of respirator performance is 6. Using point estimates at the extremes of the distribution would give an estimate of exposure of 17 (100/6). With the Monte Carlo simulation, using estimates that vary according to their underlying distributions, only 0.2% of exposures would be above an OEL.

If variability of C_o is greater than the value used in this model (GSD of 6), the effect on the risk of exposure higher than the OEL would not exceed the 5% criteria. As shown in Figure 3, as the variability of C_o increases, the percentage of concentrations for C_i that exceed the OEL decreases for situations with highly variable respirator performance (GSD of $R_{PF} > 3$).

If the variability of C_o is below a GSD of 2, and if the GSD of R_{PF} is greater than 4.5, then the percentage of the time that C_i is greater than the OEL may be above the 5% criteria. This would be the case only if the respirator were used at the MUC. The number of people who may meet these conditions is small. Less than 5% of people have R_{PF} values less than 44. For these 5%, less than 10% have a R_{PF} GSD that is greater than 4.5.

Contaminants in the workplace can have acute or chronic effects. The agent's biological half-life influences its ability to accumulate and exert a harmful effect. If the exposure limits are based on the biological half-life, and the half-life is longer than a week, then the mean of exposures is important in estimating risk.(10) If the mean is less than the OEL, for the slow acting toxicants the risk of health effects is minimized. For the case discussed in the preceding paragraph, the percentage of time the mean C_i concentration is above the OEL is much less than the data presented in Figure 4.

Rappaport(10) demonstrated that if a person is exposed with a mean concentration less than 25% of a STEL, exposures would not exceed the STEL more than 5% of the time. In this analysis, the maximum mean concentration was 30% of the OEL.

CONCLUSION

A model of respirator performance was constructed to assess respirator performance by calculating the concentration inside the respirator. Estimates of the factors that effect respirator performance were described as distributions. The distributions used a worst case estimate for C_o, the worst case for R_{PF} (the fifth percentile person), and the worst case for exhalation valve leakage. A Monte Carlo analysis then provided estimates of the percentage of time that C_i exceeds the OEL. For a half facepiece with an APF of 10, the calculations indicated a low risk of being exposed above an OEL, with mean exposures being controlled well below an OEL.

The analysis is easy to perform. To perform the analysis for other respirator types, values for respirator performance need to be estimated. The values for C_o used in this analysis could be changed by assuming the other respirator's APF.

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