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Dear Dr. Amendola:

I understand that you have invited comments concerning issues for discussion at a respirator conference to be held in Morgantown on January 9-11,1991. I further understand that a general focus is the appropriate derivation of assigned protection factors for particular respirator units or respirator classes. I would like to offer a brief comment concerning the analysis and interpretation of workplace protection factor (WPF) data. The same comment applies to simulated WPFs or laboratory WPFs, whatever one chooses to call protection factors measured under simulated workplace conditions.

A common WPF study design is to select a number of individuals from a group of respirator wearers and to make several WPF measurements on each of the selected individuals. The typical data analysis involves aggregating all these measured WPFs into one distribution (typically assumed to be lognormal) and then determining the 5th percentile WPF value. In its 1987 Respirator Decision Logic, NIOSH recommended equating the assigned protection factor (APF) for the respirator with this point estimate of the 5th percentile WPF value. From my reading of the respirator literature, I seem to be the only person who has questioned the appropriateness of this APF derivation. My reason is the following.

The aggregate data analysis described above implies that, in essence, all wearers have an identical WPF distribution. However, nearly all WPF data sets show substantial variability *between* wearers in the average level of respiratory protection. In support, please find enclosed a paper I wrote that describes a one-way analysis of variance performed on two separate NIOSH WPF data sets for powered air-purifying respirators. Please also note that a paper by Galvin, et al., presenting a similar analysis of WPF data for air-purifying halfmask respirators will appear in the December 1990 issue of the *American Industrial Hygiene Association Journal*.

In part due to this between-wearer variability in respiratory protection, the 5th percentile of an aggregate WPF distribution has little meaning. It does *not* represent every wearer's 5th percentile WPF value, *nor* does it represent the minimum WPF value for 5% of wearers. Therefore, an assigned protection factor (APF) equated with the 5th percentile of an aggregate WPF distribution also has little meaning. Further, if the maximum use concentration is taken as the product of this APF and the permissible exposure limit, then a substantial number of respirator wearers can be overexposed to the toxicant.

In collaboration with Dr. Robert Spear, Professor of Environmental Health Sciences at the University of California-Berkeley, I will this month be submitting two papers to the *AIHA Journal* which present a mathematical model

describing the distributions of inside-the-facepiece contaminant levels (C_i) for a population of respirator wearers. This model accounts for *within-wearer* and *between-wearer* variability in ambient contaminant levels (C_o) and and respirator penetration (P) values. The model expands on the simple fact that: $C_i = C_o \times P$. I would be happy to provide you with copies of these manuscripts once they are formally submitted.

I mention these manuscripts because they relatively succinctly describe a complex situation and speak to the issue of setting assigned protection factors and maximum use concentrations. In particular, in setting a maximum use concentration, one needs to reach a consensus on the statistical definitions of the permissible exposure limit and the notion of "overexposure," and also reach a consensus on the acceptable "population risk," which is the proportion of the population permitted to be "overexposed." At least, that's how I see it.

Thank you for considering these comments.

Sincerely,

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The Assigned Protection Factor: Statistical Aspects of Its Definition and Implications for Risk Management

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In the past five years there has been a dramatic increase in the number of respirator field studies, and the generation of Workplace Protection Factor (WPF) data has encouraged efforts to set Assigned Protection Factors (APF). Contributing to a consensus in terminology, both NIOSH and the AIHA Respiratory Protection Committee proposed similar definitions for the APF.

This is the NIOSH definition proposed several years ago, and it's basically the same one used in the 1987 NIOSH Respirator Decision Logic.

ASSIGNED PROTECTION FACTOR (NIOSH)

> "a measure of the minimum anticipated level of respiratory protection that would be provided, by a properly functioning respirator, to a large percentage of properly fitted and trained wearers. The maximum use concentration for a respirator is generally determined by multiplying a contaminant's PEL (or TLV) by the protection factor assigned to the respirator."

I note two things about this definition:

1) It calls the APF the minimum anticipated protection for a large percentage of users.
2) It defines the Maximum Use Concentration as the APF x PEL (or TLV).

For WPF data from a sample of wearers, NIOSH has recommended equating the APF with the 5th percentile of the WPF values. In other words, we would expect that, loosely speaking, 95% of WPF's achieved by the user population would exceed the APF value.

However, this definition implies two conditions which I will show are incorrect given the statistical model used to derive the APF:

First, that 95% of wearers passing a fit test will achieve a WPF≥ APF during 100% of respirator use periods; and second, that an individual passing a fit test has a 95% probability of having a minimum WPF≥ APF.

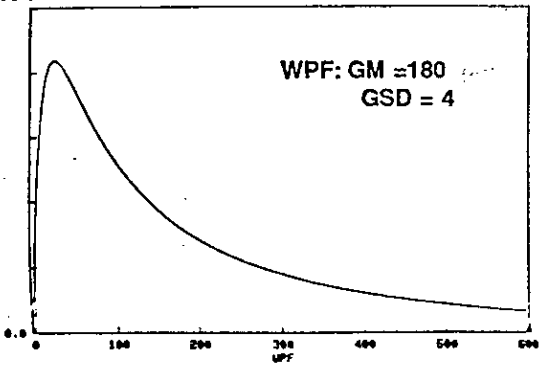
I will also show that a proper definition of the APF involves determining the within-user and between-user components of the total variability in the population WPF's. In turn, the presence or absence of average WPF differences between users will affect the health risk for a population wearing the respirator at the Maximum Use Concentration.

In almost all published field studies, a two-parameter lognormal distribution has been used to describe the WPF's. This model has been used for:

1) replicate WPF's for a single wearer
2) single WPF's for multiple wearers; and
3) grouped replicate WPF's for multiple wearers.

Graph 1 shows a two-parameter lognormal WPF distribution. Its values range from zero to infinity and it's completely described by its Geometric Mean and Geometric Standard Deviation. In this case the GM = 180 and the GSD = 4.

DISTRIBUTION OF WORKPLACE PROTECTION FACTORS



Graph 1

Although most reports use a two-parameter model, WPF's are better described by a three-parameter distribution truncated in the right tail. The third parameter, termed K, is the location parameter or minimum value, and should be greater than or equal to 1 since it is physically impossible to have a WPF less than 1.

The truncation point should equal the inverse of the decimal fraction contaminant penetration through the air-purifying element. For a high-efficiency filter removing 99.97% of submicron particles, this initial truncation point might be 3300. However, for the calculations in this talk I've used the two-parameter model, which simplifies computations and leads to negligible errors.

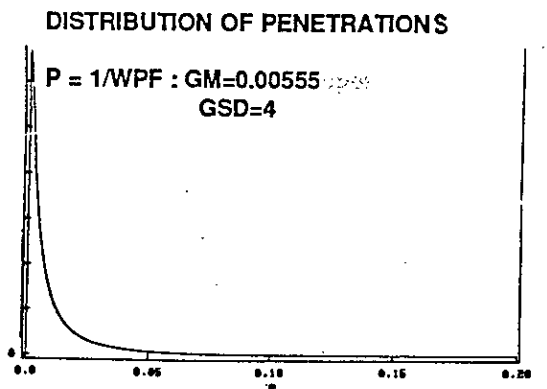
Although most everyone talks in terms of protection factors, I'm going to switch gears for the moment and talk about the Penetration which is the inverse of the protection factor. By investigating the distributions of Penetration values and of ambient contaminant levels, we can derive the distribution of contaminant concentrations inside the respirator. It is the latter set of values that allows us to assess health risk for the respirator wearer.

If WPF's are lognormally distributed, then theory tells us that the corresponding inverse values, or Penetrations, are also lognormal with the same GSD and with a Geometric Mean equal to the inverse of the Geometric Mean WPF, i.e.

> If WPF's are lognormally distributed with GM = exp (u_ℓ) and GSD = exp (σ_ℓ), then values of penetration (p = 1/WPF) are also lognormally distributed with GM = exp ($-u_\ell$) and GSD = exp (σ_ℓ).

For the WPF distribution previously shown, the Penetration values are shown in Graph 3. They're also right skewed and range in value from zero to one.

(Note: P = 1 corresponds to K = 1 for the WPF distribution).



Graph 2

The Penetration variable is useful because a basic theorem of the respirator business is that the contaminant concentration inside the respirator (Ci) is directly related to the Penetration (P) and the contaminant concentration outside the respirator (Co). → $C_i = C_o \cdot P$

The current view is that both Co and P are lognormally distributed variables, and most respirator researchers believe they're statistically independent. If these assumptions are true...

$$\ln C_i = \ln C_o + \ln P$$

...then theory tells us that the log-transformed variables shown in this equation are normally distributed. Therefore, Ci itself is a lognormal variable. In this case...

$$E(\ln C_i) = E(\ln C_o) + E(\ln P)$$

$$GM(C_i) = \exp [E(\ln C_o) + E(\ln P)]$$

...the geometric Mean of Ci is equal to the antilog of the right side of the top equation shown here...

$$Var(\ln C_i) = Var(\ln C_o) + Var(\ln P)$$

$$GSD(C_i) = \exp [\sqrt{Var(\ln C_o) + Var(\ln P)}]$$

...and the Geometric Standard Deviation of Ci is equal to the antilog of the square root of the right side of the top equation shown here. I note that if Co and P are not statistically independent, then one needs a covariance term in this formula.

$$E(C_i) = E(C_o) \times E(P)$$

Finally, if Co and P are independent, it's also true that the Arithmetic Mean of Ci is the product of the Arithmetic Mean of Co and P.

Therefore, by estimating the parameters of Co and P, we can derive the parameters of the lognormal distribution of Ci. Further, we can use these parameters to predict the relative frequency with which the inside concentration exceeds some given value.

$$Pr(C_i > X) = Pr\left[Z > \frac{\ln X - \ln GM(C_i)}{\ln GSD(C_i)}\right]$$

The above formula shows that one can use the standard normal deviate distribution to make this prediction.

EXAMPLE

1) $GM(C_o) = 50$ ppm and $GSD(C_o) = 2.0$

2) $GM(P) = .020$ and $GSD(P) = 2.0$

$GM(C_i) = 1.0$ ppm
$GSD(C_i) = 2.7$
$E(C_i) = 1.6$ ppm
$Pr(Ci>10 \text{ ppm}) = .01$

Here's an example of how it works. Let's say that ambient 8-hr TWA contaminant levels are lognormal with the parameters in item 1. Let's also say that daily Penetration values for a halfmask respirator user are lognormal with the parameters in item 2. This Geometric mean P value corresponds to a WPF = 50, and only 1% of this user's WPF's are <10.

When we do some number crunching, we find that the inside 8-hr TWA concentrations have a GM = 1 ppm, a GSD = 2.7, and an Arithmetic Mean = 1.6 ppm. If we're interested in the proportion of days that Ci exceeds the value 10 ppm, it turns out to be 1%. If 10 ppm were the Permissible Exposure Limit for this chemical, we could conclude that this user is exposed above the PEL on 1% of all workdays.

With regard to health risk, where a chemical exerts primarily chronic toxicity, we are likely concerned with keeping the Arithmetic Mean of Ci below the PEL; where a chemical exerts primarily acute toxicity, we are more concerned with limiting the relative frequency with which Ci exceeds the PEL, perhaps to 5% or only 1% of the time.

From a compliance perspective, our concern depends on how the regulatory agency statistically defines the PEL, but that is a subject deserving a talk all its own.

Now, while it's mathematically simpler to work with Penetration values, it's conceptually easier to talk in terms of integers like protection factors. So I will continue my talk in terms of WPF's. But first let me define a parameter of the wpf distribution that corresponds to the Arithmetic Mean Penetration.

$$WPF_{av} = \frac{1}{E(P)}$$

$$WPF_{av} = \frac{GM_{WPF}}{\exp[1/2(\ln GSD_{WPF})^2]}$$

I call this parameter the WPF-average. It is simply the inverse of the Arithmetic Mean Penetration. Based on the relationships between the Geometric Mean and GSD of the WPF and Penetration distributions, the WPF-average can be computed by the bottom equation.

I note that the WPF-average is less than the Geometric Mean or Arithmetic Mean of the WPF values. I also note that the WPF-average is a measure of the long-term protection afforded by a respirator.

And as shown here, we can use the WPF-average to calculate the Arithmetic Mean inside concentration.

Having laid this foundation, I'll now return to the problem I see in the current definition of the Assigned Protection Factor. $E(C_i) = \frac{E(C_o)}{WPF_{av}}$

THE NIOSH/AIHA DEFINITION IMPLIES THAT:

1) a stated percentage, say 95%, of wearers passing a fit test will attain a WPF≥APF during 100% of respirator use periods

2) an individual wearer passing a fit test has a 95% probability of having a minimum WPF≥APF

As I previously stated, this definition implies that 95% of wearers passing a fit test will attain a WPF greater than or equal to the APF during 100% of respirator use periods. Recall that the APF is termed the minimum anticipated level of protection for 95% of wearers. This also implies that if a person passes a fit test, he or she has a 95% probability of having a minimum WPF ≥ APF.

However, if a lognormal model with a location parameter = 1 describes the WPF distribution for every user, then no user has a minimum WPF equal to the APF when the APF is greater than 1. This will be true both where there are no differences in WPF's between users, and where there are differences, as long as the location parameter is 1 for all users. This fact follows from using the lognormal model to describe WPF's.

A practical consequence of using an incorrect APF definition is that employers and employees might acquire a false sense of security regarding respiratory protection. This could decrease the employer's motivation to seek feasible engineering controls, and decrease the employee's motivation to adhere to time-consuming work practices that limit ambient contaminant levels.

To determine a valid statistical definition of the APF, we need to choose between two mutually exclusive models for describing the user population WPF's:

1) All users have the same lognormal distribution of WPF's with some Geometric Mean and GSD; or
2) Different users have unique WPF distributions with different Geometric Means and/or GSD's and the WPF-averages are distributed in some manner, perhaps lognormally.

To determine which model is valid, one needs to collect multiple WPF's per user for a sample of users and perform an analysis of variance of the log-transformed WPF's. Since it's always easier to analyze someone else's data than to generate one's own, I obtained two data sets from NIOSH for helmet-and-visor type powered air-purifying respirators worn at a secondary lead smelter and a lead battery plant. I'd like to thank Warren Myers and NIOSH for making this data available to me.

Both data sets involved 12 PAPR users, with 4 WPF's determined per user for most participants. Each WPF was obtained over a wearing time of 5 to 8 hours. The aggregate WPF values in each study appeared to be lognormally distributed.

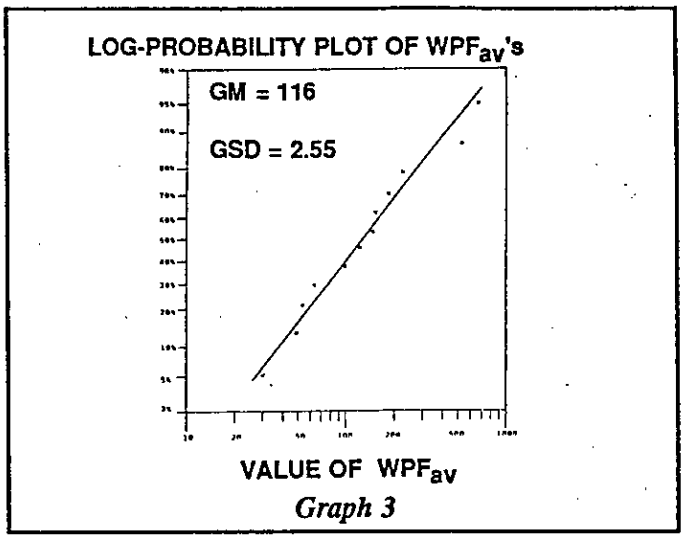
ONE WAY ANALYSIS OF VARIANCE NIOSH Pb SMELTER DATA SET

Sum of Squares	*Degrees of Freedom*	*Mean Square*
Between = 35.824	11	3.257
Within = 26.383	34	0.776
Total = 62.207	45	

$F = \frac{3.257}{0.776} = 4.2$ $p = .0006$ Reject $H_0: \mu_1 = \mu_2 = \ldots = \mu_{12}$

The preceeding is an ANOVA table for the lead smelter data set. The between-user variability accounts for about 60% of the total variability in WPF's. The null hypothesis is that the means of the log-transformed WPF's for all 12 users are equal. The null hypothesis can be rejected at a significance probability of .0006.

This finding says there are differences in the Geometric Mean WPF's between users, and by analogy, differences in the WPF-averages. Further, the variances for the individual WPF distributions are not significantly different, which says that the within-user GSD's can be treated as equal and estimated from the within mean square in the ANOVA table.



Graph 3

Graph 3 shows a log-probability plot of the estimated WPF-averages for these 12 PAPR users. The eyeball test for goodness-of-fit suggests that WPF-averages in this population are lognormally distributed with the indicated parameters.

In contrast, the following Table shows an ANOVA for the lead battery plant data set. The between-user variability accounts for only 20% of the total variability in WPF's, and the null hypothesis cannot be rejected since the significance probability is .62. As in the other data set, the variances for the individual WPF distributions are not significantly different.

ONE WAY ANALYSIS OF VARIANCE NIOSH Pb BATTERY PLANT DATA SET

Sum of Squares	*Degrees of Freedom*	*Mean Square*
Between = 8.505	11	0.773
Within = 33.045	35	0.944
Total = 41.55	46	

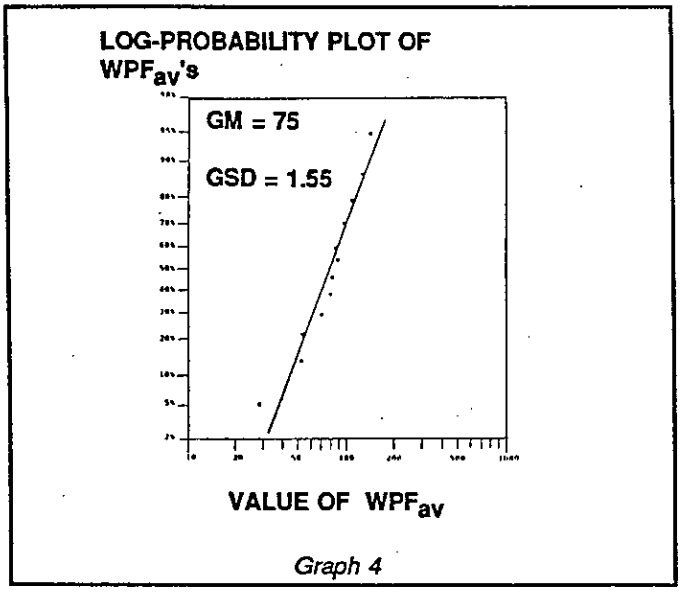
$F = \frac{0.773}{0.944} = 0.819$ $p = .62$

Do Not Reject $H_0: u_1 = u_2 = \ldots = u_{12}$

ANOVA Table

These findings say there are no differences in the Geometric Mean WPF's between users, and by analogy, no difference in the WPF-averages. Hence the parameters of the aggregate WPF distribution represent the parameters for every user's WPF's.

However, the failure to reject the null hypothesis does not prove the null hypothesis to be true. One must consider the Power of the test to demonstrate differences when differences actually exist. While I haven't calculated the Power in this case (since it's not a trivial exercise), I suspect that it's low given the small number of replicate WPF's per user. Therefore, I'm not comfortable with concluding that differences in WPF-average do not exist.



Graph 4

So I went ahead and did a log-probability plot, Graph 4, of the estimated WPF-averages. Again, the eyeball test for goodness-of-fit suggest they are lognormally distributed with the indicated parameters. Of course, the assumption of lognormality does run counter to the results of the previous hypothesis test.

ALTERNATIVE MODELS FOR THE DISTRIBUTION OF POPULATION WPF'S:

Model 1) All wearers have the same lognormal WPF distribution with some GM and GSD

or

Model 2) Different wearers have lognormal WPF distributions with different GM's and/or GSD's, and the wearer WPF_{av}'s are distributed in some manner, perhaps lognormally.

To summarize, one data set suggests that Model 1 is correct, that is, all users have the same lognormal distribution of WPF's, and the parameters of this distribution can be directly estimated from the aggregate WPF values. However, another data set suggests that Model 2 is correct, that is, different users have unique WPF distributions, and the WPF-averages are lognormally distributed.

To go out on a limb, I recommend we assume that Model 2 is generally true for air-purifying respirator wearers. It makes intuitive sense that a given respirator will provide a better fit to some wearers than to others, and that some wearers will be more diligent than others in their use of the respirator. It is also the more conservation assumption from the standpoint of establishing Maximum Use Concentrations and limiting health risk to respirator wearers.

To examine the implications of using Model 1 vs. Model 2 in analyzing WPF data to derive an APF and a Maximum Use Concentration, let's consider the lead smelter data set.

SCENARIO

1) Aggregate WPF Distribution:
GM = 167, GSD = 3.24, 5%ile = 24

2) WPF_{av} Distribution:
GM = 116, GSD = 2.55, 5%ile = 25

3) MUC = APF x PEL = 25 x 50 ug/m^3

4) Let $E(C_o)$ = MUC

The aggregate WPF distribution had the parameters shown in item 1. The estimated 5th percentile WPF was 24, and this value itself was a basis for NIOSH's recommended APF of 25 for the helmet-and-visor PAPR assembly. The WPF-average distribution has the parameters shown in item 2; as it happens, the estimated 5th percentile was also 25.

According to the Maximum Use Concentration formula in item 3, the MUC is an 8-hr TWA lead concentration of 1250 ug/m3. So let's push things to the limit and set Arithmetic Mean outside concentration equal to the MUC as shown in item 4.

MODEL 1

For every wearer:

$$WPFav = \frac{167}{\exp[1/2\ (\ln 3.24)^2]} = 84$$

$$E(C_i) = \frac{1250\ ug/m3}{84} = 15\ ug/m3$$

Under Model 1, which says that everyone is the same, every user has a WPF-average = 84. It follows that every user has an Arithmetic Mean inside lead concentration = 15 ug/m3, which is well below the PEL, so no user should be at unacceptable health risk.

MODEL 2

$E(C_i) > 50$ ug/m3 for every wearer with a $WPF_{av} < 25$

5% of wearers have an $E(C_i) > 50$ ug/m3, the Permissible Exposure Limit

However, if Model 2 is true, then any user with a WPF-average <25 will have an Arithmetic Mean inside lead concentration >50 ug/m3. But I previously said that 5% of users had a WPF-average <25. This 5% will be exposed to an Arithmetic Mean inside lead concentration greater than the PEL.

It should be clear that the health risk to a population using a respirator at the MUC varies markedly with the reality underlying the aggregate WPF data. One way to decrease the health risk is to decrease the Maximum Use Concentration. For example, if the MUC were 50% of the currently permitted level of 25 times the PEL, and if Model 2 were true for this scenario, less than 1% of the PAPR users would have an Arithmetic Mean inside lead concentration above the PEL.

The implication of model differences for respirator use against acute toxicants is even more striking. Let's consider a simple case where the ambient concentration is a constant value.

SCENARIO

1) One WPF per wearer for a sample of wearers is collected.
2) GM = 100 and GSD = 4.0
3) Let APF = 5%ile WPF = 10
4) Let MUC = APF x PEL = 10 PEL
5) Let acceptable $Pr(C_i > PEL) = .05$

Let's say that someone has gone out and measured one WPF per user for a sample of users. The WPF's are lognormal with the parameters in item 2. The APF is equated with the 5th percentile WPF value which in this case is 10. The MUC is equated with 10 times the PEL. Finally, let's set the acceptable risk of exposure above the PEL during a respirator use period at 5%.

MODEL 1

The 5%ile WPF = 10 for every wearer

When $E(C_o) \leq 10$ PEL, every wearer has $Pr(C_i \geq PEL) \leq .05$

Given this scenario, under Model 1 the estimated 5th percentile of 10 is every user's 5th percentile WPF. Therefore, as long as the outside concentration is less than or equal to the MUC of 10 times the PEL, no user is at unacceptable risk.

MODEL 2

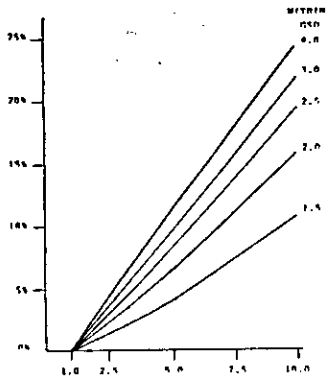
The sample GM = 100 and GSD = 4 are the estimated parameters of the WPF_{av} distribution.

No estimate is available for the GSD of the within-wearer WPF distribution.

Under Model 2, the available WPF data can be interpreted as estimating the distribution of WPF averages. That is, one randomly selected WPF for a user is a point estimate, albeit not a very good estimate, of the user's WPF-average. However, we no longer have an estimate of the GSD for the individual WPF distributions.

For simplicity we'll assume the within-wearer GSD is the same for everyone, and we'll assigned this GSD value. The percent of users at unacceptable risk can now be calculated by an algorithm based on the distribution of inside contaminant concentrations and the distribution of WPF-averages. After much number crunching the following graph results.

PERCENT OF WEARERS AT UNACCEPTABLE RISK



C_O IN MULTIPLES OF THE PEL

Graph 5

The vertical axis shows the percent of users at unacceptable risk of acute toxicant overexposure. The horizontal axis shows the value of the outside concentration ranging from 1 to 10 times the PEL. The different lines represent different values of the GSD for the individual WPF distributions. Over the GSD range of 1.5 to 4, increasing the GSD value increases the percent of users at unacceptable risk.

This graph shows that if the respirator is used at the MUC of 10 times the PEL as computed under Model 1, over 20% of users are at unacceptable risk when the GSD is greater than about 2.7. If we have the MUC to 5 times the PEL, over 10% of wearers are at unacceptable risk when the GSD is greater than about 3.0. According to the graph, if the GSD can be as high as 4 and we want no more than 5% of the wearers in this population to be at unacceptable risk, the MUC should be only 2.5 times the PEL.

So what do I conclude from all this?

CONCLUSION #1

We should assume that WPF_{av}'s are lognormally distributed in a population using an air-purifying respirator (Model 2).

In general, Model 2 predicts a higher level of health risk for a population wearing an air-purifying respirator at the MUC.

First,we should assume that there are differences in WPF-averages between users of air-purifying respirators, and we need to understand the implications of these differences for user health risk.

CONCLUSION #2

The study design should include at least 4 replicate WPF's per wearer for a sample of wearers.

Second, research is needed to determine the extent of these differences. The required study design is to have at least 4 replicate WPF's per user for a larger sample of users. If, say, only 60 WPF's can be collected in a study, it would be better to sample 6 WPF's from each of 10 users than 1 WPF from each of 60 users.

CONCLUSION #3

An Alternative APF on Definition:

"The APF is the protection factor that will usually, but not always, be met or exceeded by a properly functioning respirator while worn in the workplace by the majority of properly fitted and trained users."

Third, the APF should be less rigorously defined. I propose the following definition:

"The APF is the protection factor that will usually, but not always, be met or exceeded by a properly functioning respirator while worn in the workplace by the majority of properly fitted and trained users."

CONCLUSION #4

The Maximum Use Concentration for air-purifying respirators should be reduced to 50% of current values.

Finally, the health risk to respirator wearers should be reduced by lowering the Maximum Use Concentration and/or requiring more rigorous fit testing. To properly establish an MUC for a population, we need to know the parameters of the WPF-average distribution and the GSD value for the individual WPF distributions, and we must agree on an acceptable level of risk for the population. Given the present unknowns I would start by reducing the current MUC's for air-purifying respirators by 50%. Higher MUC's for indivi-dual wearers should be allowed only where fit testing procedures can adequately predict the necessary WPF's.