EQUATIONS FOR CALCULATING EXPOSURE MANAGEMENT OBJECTIVES

Paul Hewett Ph.D. CIH

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1 ABSTRACT

The majority of exposure limits for gases, vapors, and particulates have as their implicit or explicit goal the control of exposures for each exposed employee. One measure of compliance with this goal - for a typical single shift, TWA exposure limit (L_{TWA}) - is the probability (θ_P) that a randomly selected worker has a *95th percentile exposure* greater than L_{TWA}. In principle, the goal of an exposure assessment program should be to determine if θ_P is small, say 0.05 or less. One method for determining if this goal has been achieved is to directly estimate θ_P through the application of expensive, complex sampling strategies that require repeat sampling of randomly selected workers, followed by a components-of-variance analysis. The purpose of this paper is to present equations for calculating site specific exposure management objectives that accomplish the same goal, but in principle require simpler strategies and fewer resources to evaluate. These objectives can be calculated for both single-shift, TWA exposure limits and the less common long-term average exposure limits, and include (a) a target group exceedance fraction(θ), (b) a target group 95th percentile, (c) a target group geometric mean, and (d) a target group mean.

The author suggests that each of these exposure management objectives can be evaluated using off-the-shelf sampling strategies and robust data analysis procedures. If the site-specific control objective is met, the overall goal of exposure control for at least 95% of the employees is likewise achieved. Examples are provided for single shift exposures limits, long-term average exposure limits, and for dual limits, where both a single shift and long-term average limit apply.

One rule-of-thumb that results from this analysis is that the traditional single shift, TWA exposure limits should be interpreted statistically as the 99th percentile exposure, rather than the 95th percentile exposure as is recommended by various organizations and authorities.

2 INTRODUCTION

The overwhelming majority of exposure limits for gases, vapors, and particulates - whether they are regulatory, authoritative, or corporate limits\[a] - have as their implicit or explicit goal the control of exposures for *each* exposed employee such that are few, if any, overexposures\[b] (Hewett, 1996, 2001; Mulhausen and Damiano, 1998; CEN, 1995). The exceptions are the few long-term average exposure limits, where the goal is the control of exposures such that the long-term (e.g., yearly) mean exposure for *each* employee is maintained below the long-term limit.\[c] Single shift exposures above the long-term limit are

\[a] Regulatory limits include the Occupational Safety and Health Administration and Mine Safety and Health Administration "Permissible Exposure Limits". Authoritative limits include the American Conference of Governmental Industrial Hygienists "Threshold Limit Values", the American Industrial Hygiene Association "Workplace Environmental Exposure Levels", and The National Institute for Occupational Safety and Health "Recommended Exposure Limits".

\[b] The term "overexposure" is used here to refer to any single-shift, TWA exposure that exceeds the TWA exposure limit. This usage is consistent with the requirements or policies of numerous exposure limit setting organizations in the U.S.: OSHA, MSHA, NIOSH, ACGIH, and the AIHA, as well as elsewhere (HSE, 1999; CEN, 1995).

\[c] Until recently, the only official long-term average exposure limit for a gas, vapor, or particulate was the 3 ppm annual mean limit for vinyl chloride used by several European Union nations. For example, the United Kingdom had a dual limit: the 3 ppm annual mean limit, as well as a conventional single shift limit of 7 ppm. Single shift exposures may exceed the long-term limit, but not the single shift limit. The annual average should not exceed the long-term limit. This long-term average exposure limit was recently rescinded and replaced with a single shift, TWA limit of 3 ppm (HSC, 2002).

in principle permitted, provided the mean exposure is less than the limit.

For this paper, we will use as a measure of compliance for the typical single shift, TWA exposure limit, or L_{TWA} , the probability (θ_P) that a randomly selected worker's "95th percentile exposure" is greater than L_{TWA}. We will also assume that the exposure limit goal is largely achieved when θ_P is controlled to 0.05 or less. Similarly, for a long-term average exposure limit, or L_{LTA} , we will assume that the goal of the limit is achieved when the probability (θ_M) that a randomly selected worker's "mean exposure" is greater than the L_{LTA} is controlled to 0.05 or less.

Sampling strategies and data analysis procedures have been recommended for directly estimating θ_M, relative to a true L_{LTA}, and calculating an approximate 90% upper confidence limit for θ_M (Rappaport et al., 1995; Lyles et al., 1997a). These procedures require substantial commitments in terms of analytical sophistication and program resources (Lyles et al., 1997b), but more importantly cannot be applied to the far more common TWA exposure limits. Assuming that most employers will not devote the resources necessary to fully implement these or similar schemes - for either TWA single-shift or long-term limits - the author proposes several alternative exposure management (i.e., exposure control) objectives:

- a target group exceedance fraction - θ'
- a target group 95th percentile - $X'_{0.95}$
- a target group geometric mean - G'
- a target group mean - M'.

The purpose of this paper is to present equations for calculating these alternative *objectives*. Each, objective, in principle, can be evaluated using a minimum of resources and program sophistication. Which objective is used depends upon the preferences of the user. If the selected objective(s) is met, then both the employer and employees will be assured that the *goal* inherent in the L_{TWA} (or L_{LTA}) is also met for at least 95% of the exposed workers. Once exposure management objectives are calculated, an exposure sampling strategy can then be designed. The strategy design process is not covered in this paper, but is addressed in a related technical report (Hewett, 2005b) on predicting the field performance of exposure assessment strategies.

3 VARIABLES

L_{TWA} - exposure limit for single-shift, time-weighted average exposures
L_{LTA} - exposure limit for long-term average exposures

x - a random, full-shift exposure for a randomly selected worker in a specific exposure group
G - geometric mean for the group overall exposure profile
D - geometric standard deviation for the group exposure profile
D_b - between-worker geometric standard deviation
D_w - within-worker geometric standard deviation
ρ - group heterogeneity coefficient

$\bar{M}$ - arithmetic mean for the group exposure profile; mean of the "worker mean exposures"

Z_x - Z-value corresponding to a percentile of the group exposure profile
Z_P - Z-value corresponding to a percentile of the distribution of "worker 95th percentile exposures"
Z_M - Z-value corresponding to a percentile of the distribution of "worker mean exposures"

θ - theta; fraction of the group exposure profile that exceeds an exposure limit L
θ_P - fraction of the distribution of individual worker upper percentiles that exceed the L_{TWA}
θ_M - fraction of the distribution of individual worker mean exposures that exceed the L_{LTA}

4 BACKGROUND

Consider the situation where an employer has 100 employees that are routinely exposed to a hazardous substance. *Per year*, there are roughly 25,000 worker-days of exposure. During an ideal exposure assessment survey each and every employee would be sampled numerous times. However, it is common for employers to collect just a few exposure measurements out of the 25,000 possible measurements before reaching a decision that exposures are acceptable or not. For baseline or initial surveys, typical sampling strategies focus on characterizing the *group* exposure profile using as few measurements as possible, typically one to ten measurements per year (or longer) (Mulhausen and Damiano, 1998; CEN, 1995; Damiano, 1995). The resulting decision is then extrapolated to all workers in the exposure group, whether measured or not, and often to other similar groups as well, for one or several years into the future.

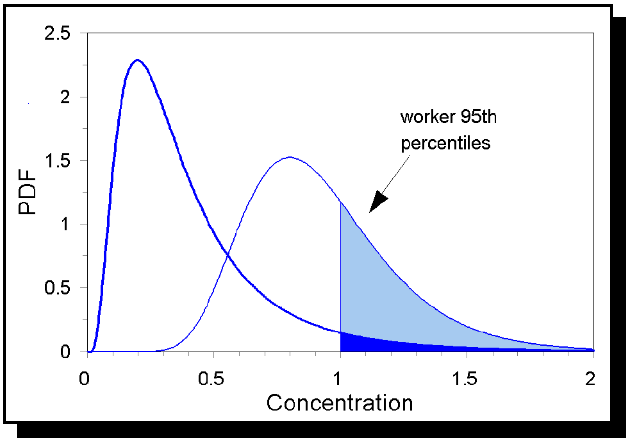

Figure 1: Distribution of worker exposures and distribution of worker "95th percentiles". The geometric mean, geometric standard deviation, and heterogeneity coefficient for the group exposure profile are 0.3197, 2.0, and 0.2, respectively. Exactly 5% of the group exposure profile exceeds the TWA exposure limit of 1 ppm. In contrast, 35% of the workers have individual 95th percentile exposures that exceed the limit.

The common assumption behind such strategies is that workers can be aggregated into "similar exposure groups" (commonly referred to as SEGs) (Mulhausen and Damiano, 1998) or "homogeneous exposure groups" (CEN, 1995) such that the exposure profiles for all or most of the workers group are similar to that of the entire group. Therefore, decisions made regarding the group exposure profile can be extrapolated to all or most of the workers in the group. As shown by Hewett (2005a), this can result in a substantial fraction of workers having individual 95th percentile exposures in excess of the L_{TWA} (or, if a long-term average limit is the issue, a substantial fraction of workers with individual mean exposures exceeding the L_{LTA}). For example, consider the situation where the 95th percentile of the exposure profile for a well defined group of workers is exactly equal to a TWA exposure limit. Let us further assume that the geometric standard deviation is 2.0 and the group is moderately heterogeneous. In this situation, as depicted in Figure 1, 35% of the workers have individual 95th percentile exposures that exceed the TWA exposure limit. (See Hewett (2005a) for the details of this calculation.)

Recognition that each worker has an individual exposure profile and that these worker exposure profiles may differ substantially from that of the entire exposure group has led to several common sense approaches to dealing with between-worker variability. Regarding TWA exposure limits, the National Institute for Occupational Safety and Health (NIOSH) in 1977 recommended that employers attempt to select "maximum risk employees" when collecting exposure measurements (Leidel et al., 1977). The basis for this recommendation was the expectation that whenever the exposures of the "maximum risk employees" are in compliance, the exposures for the remaining employees in the exposure group are most likely also in compliance. For similar reasons, the Occupational Safety and Health Administration (OSHA) routinely permits employers to select employees expected to have the "highest exposure" in lieu of sampling each and every employee.

In 1998 the American Industrial Hygiene Association (AIHA) (Mulhausen and Damiano, 1998) advanced the concept of a "critical SEG" to address between-worker variability issues. A critical SEG is one where the sample estimate of the group 95th percentile is between 50% and 100% of the TWA exposure limit. In this situation the AIHA suggests that although the exposure profile for the group *appears* to be acceptable, there may be workers that are routinely exposed at levels above the exposure limit. Consequently, additional measurements should be collected and the definition of the exposure group examined more closely. The AIHA noted that there are situations where between-worker variability is likely not an issue. For example, if the sample estimate of the group 95th percentile is considerably less than the TWA exposure limit - i.e., less than half the limit - then it is highly unlikely for a well defined exposure group that there are individual workers routinely exposed above the limit.

For true long-term average exposure limits - L_{LTA} - Rappaport et al. (1995) devised an approach that deals explicitly with between- and within-worker variability. They recommended that at least ten randomly selected workers be sampled two or more times each year. The resulting dataset would then be analyzed using several *ad hoc* procedures and components-of-variance methods (for example, see Lyles et al. (1997a)) to determine if θ_M is highly likely to be less than their suggested critical value of 0.10. In other words, Rappaport et al. recommended that at least 90% of the workers have an individual exposure profile mean that is less than the long-term limit. However, as shown by Lyles et al. (1997b), for a wide range of plausible exposure scenarios the number of measurements actually needed to demonstrate compliance, using this scheme, will often far exceed the recommended 20 baseline measurements.\[d] This begs the question, is there a cheaper, simpler way to ensure that θ_M is appropriately controlled?

In summary, there are no published procedures for explicitly ensuring that, say, 95% of the workers in an exposure group have an individual 95th percentile exposure that is less than a TWA exposure limit, and the one published procedure for long-term average exposure limits is expensive, complex, and cannot be applied to TWA exposure limits. In this paper, the components-of-variance (COV) model presented by Hewett (2005a) is used to derive exposure management objectives for the group exposure profile. If these objectives can be routinely achieved both the employer and employees will have assurance that the exposure profiles are acceptable for nearly all workers in the group.

Readers should note that the focus of this paper is on the calculation of site or process specific exposure management objectives. The design of a site or process specific exposure assessment strategy and data analysis scheme is left to the reader. However, the author suggests that strategies and data analysis schemes such as those recommended by the AIHA (Mulhausen and Damiano, 1998) and the CEN (1995) could be easily adapted for use with these exposure management objectives. Generic issues that one should consider when designing an exposure assessment strategy are discussed in a related paper (Hewett, 2005b).

5 THE COMPONENTS OF VARIANCE MODEL

The COV model presented by Hewett (2005a) is completely described by the following relation:

$$x \sim L(G, D, \rho)$$

which translates as x, a random exposure from a randomly selected worker, is lognormally distributed with group geometric mean (G), group geometric standard deviation (D), and a group heterogeneity coefficient (ρ). This model is nearly identical to a conceptual model already developed for long-term average exposure limits (e.g., see Spear and Selvin (1989) or Lyles et al. (1997a), but has been extended so that it can be applied to the single shift, TWA exposure limits that most industrial hygienists encounter on a daily basis. Like all models, this one has deficiencies (Hewett, 2005a), but is close enough for us to be able to generalize and examine relationships between various measures of exposure profile acceptability.

The following equations will serve as building blocks for the equations presented later.

5.1 Group variability

We will assume that the exposure profiles for all the workers in an exposure group are sufficiently alike that we can use the same geometric standard deviation (D_w) as an indicator of variability for each worker. We also assume that each worker has their own unique, lognormal exposure profile with a unique geometric mean. The distribution of these individual worker geometric means is also lognormal with variability indicated by a between-worker geometric standard deviation (D_b). The overall variance, on the log scale, is a function of the between-worker variance and the within-worker variance:

$$\ln D = \sqrt{(\ln D_b)^2 + (\ln D_w)^2}$$

For the sake of convenience, let us define a variable ρ that represents the ratio of the between-worker variability to the total variability:

\[d] Furthermore, their method fails to accurately estimate the 90% UCL for θ_M for exposure groups where there is moderate to low between-worker variability (Lyles et al., 1997b).

$$\rho = \frac{(\ln D_b)^2}{(\ln D_b)^2 + (\ln D_w)^2} = \frac{(\ln D_b)^2}{(\ln D)^2}$$

This "heterogeneity coefficient" ranges between 0 and 1. As discussed in Hewett (2005a) typical low, medium, and high values of ρ can provisionally be set at 0.05, 0.20, and 0.40. These values were derived from the work of Kromhout et al. (1993).

5.2 Group Mean

The true or population mean of the group exposure profile ($\bar{M}$) - i.e., the mean of the "worker means" - can be calculated from the group geometric mean and geometric standard deviation using the following standard equation (Leidel et al., 1977):

$$\bar{M} = \exp\left(\ln G + \frac{1}{2}\cdot\ln^2 D\right) = G\cdot\exp\left(\frac{1}{2}\cdot\ln^2 D\right) \qquad \text{Eq. 1}$$

5.3 Group Percentiles

The 95th percentile ($X_{0.95}$) of the group exposure profile, the 95th percentile "worker 95th percentile" exposure ($P_{0.95}$), and the 95th percentile "worker mean" exposure ($M_{0.95}$) can be calculated using the following equations:

$$X_{0.95} = \exp\left(\ln G + Z\cdot\ln D\right) \qquad \text{Eq. 2}$$

where Z=1.645

$$P_{0.95} = \exp\left[\left(\ln G + 1.645\cdot\sqrt{1-\rho}\cdot\ln D\right) + Z_P\cdot\sqrt{\rho}\cdot\ln D\right] \qquad \text{Eq. 3}$$ \[e]

where Z_P=1.645

$$M_{0.95} = \exp\left[\left(\ln G + \frac{1}{2}(1-\rho)\cdot(\ln D)^2\right) + Z_M\cdot\sqrt{\rho}\cdot\ln D\right] \qquad \text{Eq. 4}$$ \[f]

where Z_M=1.645.

Other percentiles can be calculated by substituting the appropriate value for Z, Z_P, or Z_M.

5.4 Calculation of Exceedance Fractions θ, θ_P, and θ_M

The group exceedance fraction θ can be calculated from the following equation:

$$\theta = 1 - \Phi\left[\frac{\ln L - \ln G}{\ln D}\right] \qquad \text{Eq. 5}$$

where L is the exposure limit; i.e., L_{TWA} or L_{LTA}.

Similarly, the fraction (θ_P) of all group workers having a 95th percentile exposure greater than a L_{TWA}, or the fraction (θ_M) of all group workers having a mean exposure greater than a L_{LTA}, can be determined from the following equations:

$$\theta_P = 1 - \Phi\left[\frac{\ln L_{TWA} - \left(\ln G + 1.645\cdot\ln D_w\right)}{\ln D_b}\right] \qquad \text{Eq. 6}$$

\[e] As ρ approaches zero, $P_{0.95}$ approaches $X_{0.95}$.

\[f] As ρ approaches zero, $M_{0.95}$ approaches the group mean $\bar{M}$.

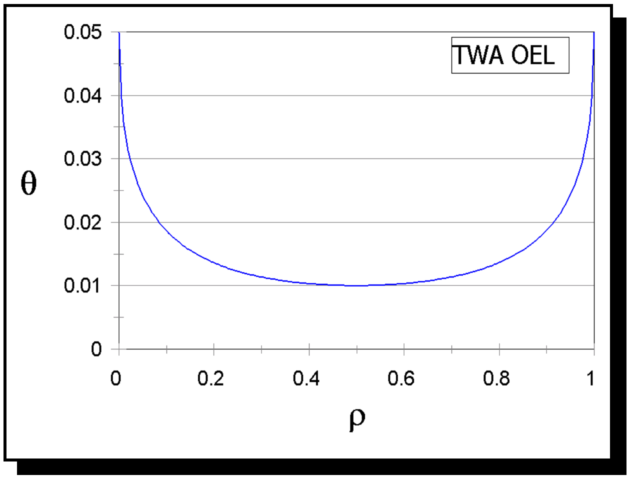

Figure 2: Probability (θ) of a random exposure from a randomly selected worker exceeding the L_{TWA} versus group heterogeneity coefficient (ρ). The curve was calculated using Equation 9 for the situation where the probability of a "worker 95th percentile" exceeding L_{TWA} is fixed at 0.05.

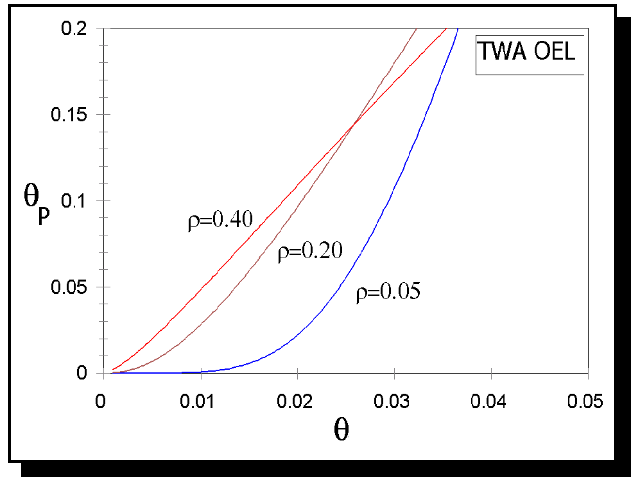

Figure 3: Probability (θ_P) of a "worker 95th percentile" exposure exceeding the L_{TWA} versus the probability (θ) of a measurement from a randomly selected worker exceeding the L. Curves for low, medium, and high heterogeneity coefficients are presented and were calculated using Equation 10.

$$\theta_M = 1 - \Phi\left[\frac{\ln L_{LTA} - \left(\ln G + \frac{1}{2}\cdot\ln^2 D_w\right)}{\ln D_b}\right] \qquad \text{Eq. 7}$$

The argument of the Φ function, i.e., the quantity in the brackets, has a Z ~ N(0,1) distribution. The fraction of the Z distribution to the left of the argument can be obtained from any Z table found in statistics texts, or from the inverse Z function found in nearly all computer spreadsheet programs.

6 CONTROL OBJECTIVES FOR SINGLE SHIFT, TWA EXPOSURE LIMITS

In the first serious discussion of exposure sampling strategies, NIOSH (Leidel et al., 1997) stated that in principle each employer should be at least 95% confident that workers experience no than 5% overexposures relative to the OSHA Permissible Exposure Limit (PEL). Corn and Esmen (1989) suggested that the fraction of overexposures for the entire exposure group (they used the term "exposure zone") be 0.05 or less. The AIHA Exposure Assessment Strategies Committee in 1991 and 1998 suggested that for a reasonably homogeneous exposure group it is appropriate to set an objective of reducing exposures to the point that the true group exceedance fraction is no more than 0.05 (Mulhausen and Damiano, 1998; Hawkins et a., 1991). The European Union in 1995 published similar guidance in a monograph on exposure assessment (CEN, 1995).

As discussed earlier, such an objective may not result in the exposure limit goal being achieved - even small amounts of group heterogeneity can result in a substantial fraction of workers having an individual 95th percentile greater than the exposure limit. *The following equations permit the calculation of control objectives that, when achieved, will help ensure that 95% of the workers have a 95th percentile exposure less than the single shift exposure limit L_{TWA}.* If necessary, the equations can be modified for other percentiles.

6.1 Calculation of a target group exceedance fraction (θ′)

Let us hypothesize a group exposure profile where the true 95th percentile "worker 95th percentile" exposure is exactly equal to a L_{TWA} (i.e., θ_P = 0.05) and that we are interested in the corresponding group exceedance fraction θ for any particular heterogeneity coefficient ρ. The general equation, which applies to all percentiles, can be derived by setting Equations 2 and 3 equal to each other and solving for Z:

$$Z = 1.645\sqrt{1-\rho} + Z_P\sqrt{\rho} \qquad \text{Eq. 8}$$

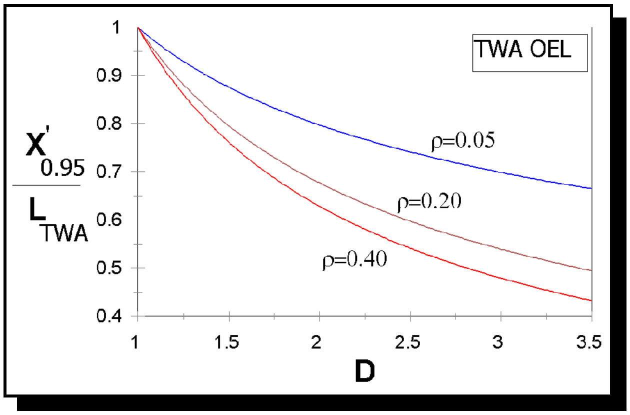

Figure 4: Ratio of target group 95th percentile exposure ($X'_{0.95}$) to the L_{TWA} versus the group geometric standard deviation (D). Curves were calculated using Equation 11.

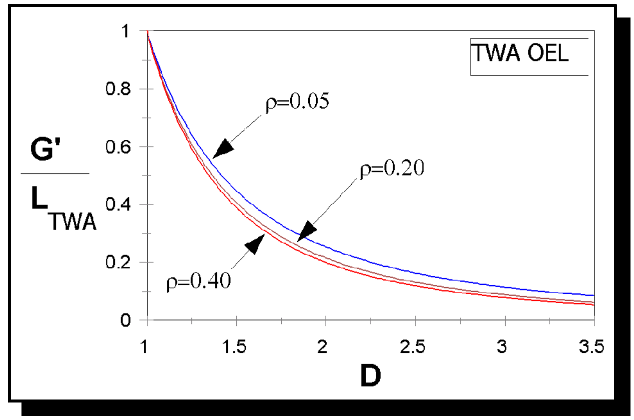

Figure 5: Ratio of a geometric mean exposure limit (G) to the L_{TWA} versus the group geometric standard deviation (D). Curves were calculated for low, medium, and high heterogeneity coefficients using Equation 12.

where Z_P = 1.645.

Using Z, the group exceedance fraction can be determined for any value of ρ:

$$\theta = 1 - \Phi[Z] = 1 - \Phi\left[1.645\sqrt{1-\rho} + 1.645\sqrt{\rho}\right] \qquad \text{Eq. 9}$$

The above relationship is graphed in Figure 2. Note that this relationship is independent of group D. As ρ approaches either 0 or 1, the group exceedance fraction θ approaches 0.05. As ρ approaches 0.5 the group exceedance fraction θ must decrease to approximately 0.01 in order to maintain θ_P at 0.05. We conclude that if the *true* exposure group exceedance fraction θ can be maintained below a target group exceedance fraction (θ′; pronounced "theta prime") of 0.01, then regardless of either D or ρ, no more than 5% of the workers will have individual 95th percentile exposures that exceed L_{TWA}. From this discussion, it follows that it is logical to think of the L_{TWA} as the 99th percentile exposure rather the more commonly accepted 95th percentile exposure.

The above equations can be manipulated so that a more general graph can be produced. Figure 3 shows the relationship between θ and θ_P , for ρ=0.05, 0.20, and 0.40. It can be seen that when θ=0.05, θ_P exceeds 0.20 for the values of ρ selected. When θ=0.01, θ_P ranges from <0.001 to 0.048, which is consistent with Figure 2. Figure 3 can be produced by starting with θ and determining the corresponding Z-value. Next, calculate the corresponding Z-value for θ_P (using Equation 8 rearranged to solve for Z_P); and then convert this Z-value to θ_P :

$$Z = \Phi^{-1}[1 - \theta]$$

$$Z_P = \frac{Z - 1.645\cdot\sqrt{1-\rho}}{\sqrt{\rho}}$$

$$\theta_P = 1 - \Phi[Z_P] \qquad \text{Eq. 10}$$

6.2 Calculation of a target group 95th percentile ($X'_{0.95}$)

It is possible to calculate a target group 95th percentile ($X'_{0.95}$) such that whenever the true group 95th percentile exposure is less than or equal to $X'_{0.95}$, the fraction of "worker 95th percentiles" exceeding L_{TWA} is constrained to 0.05 (i.e., $\theta_P = 0.05$). Set Equation 2 equal to $X'_{0.95}$ and Equation 3 equal to L_{TWA}. Solve both equations for lnG and then set them equal to each other. Rearranging results in the following equation:

$$\frac{X'_{0.95}}{L_{TWA}} = \exp\left[1.645 \cdot \ln D - 1.645\sqrt{1-\rho} \cdot \ln D - 1.645\sqrt{\rho} \cdot \ln D\right] \qquad \text{Eq. 11}$$

Figure 4 shows this relationship for various values of D. Compliance with $X'_{0.95}$ 95% of the time virtually guarantees that θ_P will be less than or equal to 0.05.

6.3 Calculation of a target group geometric mean (G′) or arithmetic mean ($\bar{M}'$)

Suppose we are interested in setting a maximum G or $\bar{M}$ for the group exposure profile, such that θ_P is constrained to 0.05. Stated another way, how low does the group G or $\bar{M}$ have to be in order to reduce θ_P to 0.05 or below? Set Equation 3 equal to the L_{TWA} and solve for G′:

$$G' = \exp\left(\ln L_{TWA} - 1.645\sqrt{1-\rho} \cdot \ln D - 1.645\sqrt{\rho} \cdot \ln D\right) \qquad \text{Eq. 12}$$

θ_P will be less than or equal to 0.05 whenever the group geometric mean is routinely controlled to less than or equal to G′. Equation 12, rearranged to solve for G'/L_{TWA}, is graphed in Figure 5. The corresponding group mean can be calculated by substituting the above equation into Equation 1:

$$\bar{M}' = \exp\left(\ln L_{TWA} - 1.645 \cdot \sqrt{1-\rho} \cdot \ln D - 1.645 \cdot \sqrt{\rho} \cdot \ln D\right) \cdot \exp\left(\frac{1}{2} \cdot \ln^2 D\right) \qquad \text{Eq. 13}$$

These two equations allow one to estimate the upper end of the target range for G and $\bar{M}$ for the group exposure profile.

6.4 Example

Say we are interested in controlling exposures relative to the OSHA benzene PEL of 1 ppm. OSHA has stated that there should be few, if any, overexposures (OSHA, 1987). Say we also know from long experience that for the group in question a group geometric standard deviation D greater than 2 is unlikely. We do not have any site specific information regarding the group heterogeneity coefficient ρ, so we will assume a fairly heterogeneous exposure group and set ρ=0.40. Given this information, we can use Figures 2, 4, and 5, or the corresponding equations, to determine the following control objectives (rounded downwards from the calculated values):

- $\theta' \le 0.01$ [\g]
- $X'_{0.95} \le 63\%$ of L_{TWA}
- $G' \le 20\%$ of L_{TWA}

Using these as objectives for a company exposure assessment and control program, resource efficient and simpler exposure sampling strategies and decision logics could be devised, using perhaps the guidelines published by the AIHA (Mulhausen and Damiano, 1998) or the European Union (CEN, 1995). For example, using the AIHA model, 6 to 10 measurements could be collected from an exposure group. From the data either the group exceedance fraction or group 95th percentile exposure would then be estimated and compared to θ′ or $X'_{0.95}$, respectively. (As with all sampling strategies, additional measurements may be necessary before making a highly confident decision, depending upon how close the group exposure profile is the control objective.)

[\g] This is equivalent to saying that the exposure group's true 99th percentile should less than or equal to the L_{TWA}.

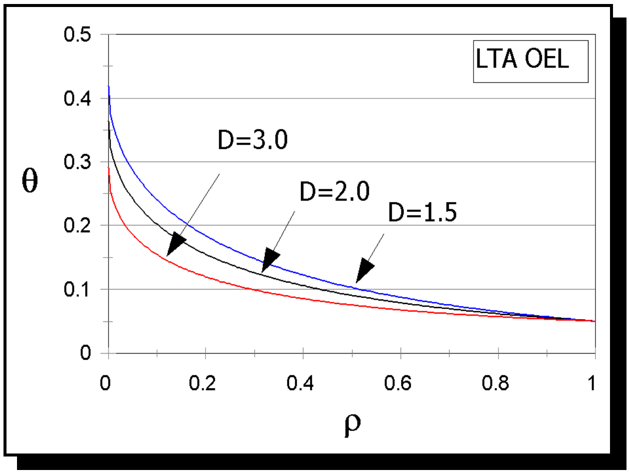

Figure 6: Probability (θ) of a random exposure from a randomly selected worker exceeds the L_{LTA} versus the group heterogeneity coefficient (ρ). Curves were calculated for low, medium, and high group geometric standard deviations, using Equation 15 for the situation where θ_M is fixed at 0.05.

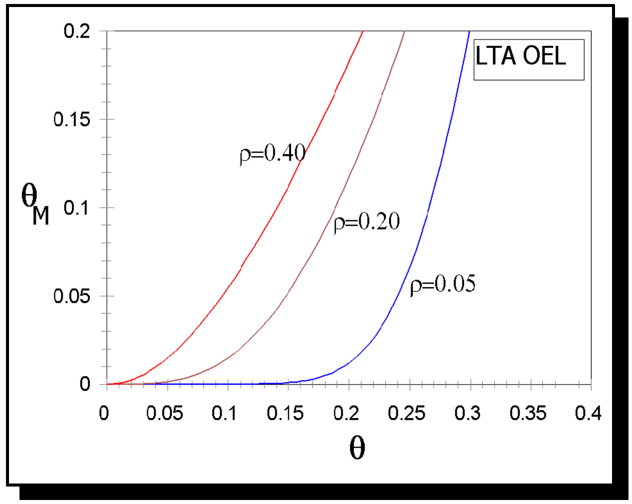

Figure 7: Probability (θ_M) of a "worker mean" exposure exceeding the L_{LTA} versus the probability (θ) of a measurement from a randomly selected worker exceeding the L_{LTA}. A group geometric standard deviation of 2.0 was assumed. Curves for low, medium, and high heterogeneity coefficients are presented, and were calculated using Equation 16.

If regular monitoring occurs, then a comparison of the point estimate would be sufficient. The upper confidence limit[h] for the point estimate should be used for comparison (see Mulhausen and Damiano, 1998) whenever monitoring is irregular or a decision must be made with high confidence. Alternatively, one could compare the estimate of the group geometric mean (or its upper confidence limit) to G′. Even a strategy based on a simple control chart could be used. For example, control limits could be placed at $X'_{0.95}$ and G′. If exposures are properly controlled, then no more than 5% of the measurements (collected from randomly selected workers) should be permitted to exceed $X'_{0.95}$, and 50% or more of the measurements should be below G′. (Also, no more than 1% of the exposures should exceed the L_{TWA}.) If both objectives can consistently be met, then we have reasonable assurance that the goal of $\theta_P \leq 0.05$ is also consistently met.

OSHA also stated that the long-term average exposure for each worker should be "well below" the PEL (OSHA, 1987). Using Equation 13 we can calculate the upper limit for the true group mean. It should be no more than 23% of the L_{TWA}.

7 CONTROL OBJECTIVES FOR LONG-TERM AVERAGE EXPOSURE LIMITS

As discussed earlier, Lyles et al. (1997a) published a sampling strategy and data analysis scheme for true, long-term average exposure limits. The default version of this scheme is complex, the confidence level is not consistent, and far more than the default number of measurements may be necessary whenever the true group ρ is less than 0.20 (Lyles et al., 1997b). The following equations permit the calculation of alternative control objectives that will help will ensure that 95% of the workers have a mean exposure less than the long-term average exposure limit L_{LTA} , yet in principle can be assessed using currently available sampling strategies.

7.1 Calculation of a target group exceedance fraction (θ′)

Let us hypothesize a group exposure profile where θ_M is equal to 0.05. The corresponding θ′, or target group exceedance fraction, can be determined by setting Equations 2 and 4 equal to each other and solving for Z :

[h] The upper confidence limit for the sample estimate of either θ or $X_{0.95}$ can be calculated using standard procedures (Mulhausen and Damiano, 1998).

$$Z = \frac{1}{2}(1-\rho)\cdot \ln D + Z_M \cdot \sqrt{\rho} \qquad \text{Eq. 14}$$

where Z_M=1.645.

Using Z, the group exceedance fraction (θ) corresponding to the scenario where θ_M=0.05 can be determined for any value of ρ and D :

$$\theta = 1 - \Phi[Z]$$

$$= 1 - \Phi\left[\frac{1}{2}(1-\rho)\cdot \ln D + 1.645\cdot\sqrt{\rho}\right] \qquad \text{Eq. 15}$$

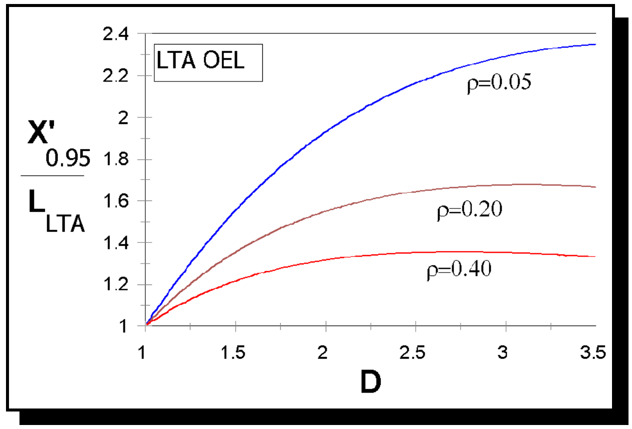

Figure 8: Ratio of target group 95th percentile exposure ($X'_{0.95}$) to the L_{LTA} versus the group geometric standard deviation (D). Curves were calculated using Equation 16.

This equation is graphed in Figure 6 for group geometric standard deviations of 1.5, 2, and 3. Given this range of typical D values, and considering that a ρ of 0.4 represents the upper end for group heterogeneity, then a general rule can be proposed: the fraction of individual worker means (θ_M) exceeding the L_{LTA} can be constrained to 0.05 whenever θ, the fraction of the group exposure profile exceeding the L_{LTA} , is maintained below a θ'_x of 0.10.

The above equations can be manipulated so that a more general graph can be produced. Figure 7 shows the relationship of θ' to θ_M for ρ=0.05, 0.20, and 0.40. A group D of 2 was assumed. It can be seen that when θ'=0.10, θ_M ranges from <0.001 to approximately 0.05, as expected. Figure 6 can be produced by starting with θ and determining the corresponding Z-value.

Next, calculate the Z-value for θ_M (using Equation 14, but rearranged to solve for Z_M); and then convert this Z-value to θ_M :\[i]

$$Z = \Phi^{-1}[1 - \theta]$$

$$Z_M = \frac{Z - \frac{1}{2}\cdot\sqrt{1-\rho}\cdot \ln D}{\sqrt{\rho}}$$

$$\theta_M = 1 - \Phi[Z_M] \qquad \text{Eq. 16}$$

7.2 Calculation of a target group 95th percentile ($X'_{0.95}$)

It is possible to calculate a target group 95th percentile ($X'_{0.95}$) such that whenever the true group 95th percentile exposure is less than or equal to $X'_{0.95}$, the fraction of "worker means" exceeding L_{LTA} is constrained to 0.05 (i.e., θ_M = 0.05). The appropriate equation can be derived by setting Equation 4 equal to L_{LTA} and Equation 2 equal to ($X'_{0.95}$. Solve both equations for lnG, and set equal to each other. Rearranging and combining terms results in the following equation:

$$\frac{X'_{0.95}}{L_{LTA}} = \exp\left[1.645\cdot \ln D - \frac{1}{2}(1-\rho)\cdot(\ln D)^2 - 1.645\sqrt{\rho}\cdot \ln D\right] \qquad \text{Eq. 17}$$

Figure 8 shows this relationship for various values of D and ρ. This equation would be useful where you are fairly certain that neither the group geometric standard deviation (D) nor the variability coefficient (ρ) exceed specific values. Compliance with $X'_{0.95}$ 95% of the time virtually guarantees that θ_M will be less than or equal to 0.05.

\[i] The above equations produce a graph equivalent to Figures 3 and 4 in Selvin and Spear (1989).

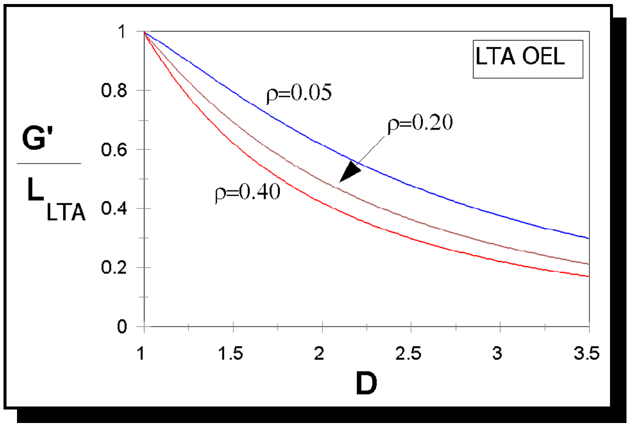

Figure 9: Ratio of a geometric mean exposure limit (G) to the L_{LTA} versus the group geometric standard deviation (D). Curves were calculated for low, medium, and high heterogeneity coefficients using Equation 18 for the situation where θ_M is fixed at 0.05.

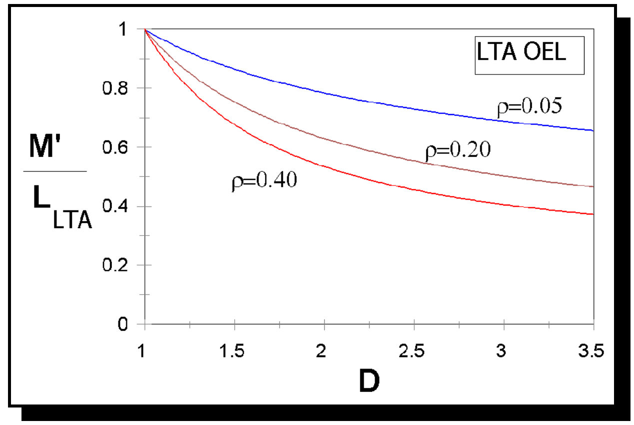

Figure 10: Ratio of a mean exposure limit (M′) to the L_{LTA} versus the group geometric standard deviation (D). Curves were calculated for low, medium, and high heterogeneity coefficients using Equation 19 for the situation where θ_M is fixed at 0.05.

7.3 Calculation of a target group geometric mean (G′) or arithmetic mean ($\bar{M}'$)

It is possible to calculate control goals for G or $\bar{M}$ such that the fraction of individual worker means (θ_M) is constrained to some tolerable level. Set Equation 4 equal to the L_{LTA} and solve for G′:

$$G' = \exp\left(\ln L_{LTA} - \frac{1}{2}\cdot(1-\rho)\cdot\ln^2 D - 1.645\cdot\sqrt{\rho}\cdot\ln D \right) \qquad \text{Eq. 18}$$

The corresponding mean can be calculated by substituting the above equation into Equation 1:

$$\bar{M}' = \exp\left(\ln L_{LTA} - \frac{1}{2}\cdot(1-\rho)\cdot\ln^2 D - 1.645\cdot\sqrt{\rho}\cdot\ln D \right)\cdot\exp\left(\frac{1}{2}\cdot\ln^2 D \right) \qquad \text{Eq. 19}$$

Equations 18 and 19, rearranged slightly to solve for G'/L_{LTA} and $\bar{M}'/L_{LTA}$, respectively, are graphed in Figures 8 and 9. As discussed previously in the section on single shift exposure limits, these two equations allow us to estimate the upper end of the target range for G and $\bar{M}$ for the group exposure profile. The routine control of the group geometric mean to G (or the group mean to M′) will virtually guarantee that θ_M will be less than or equal to 0.05.

7.4 Example

Say we are interested in controlling exposures relative to a corporate long-term average exposure limit. As before, let us assume that a group geometric standard deviation D greater than 2 is unlikely and that ρ is expected to be 0.40 or less. Given this information, we can use Figures 6, 8, 9, and 10, or the corresponding equations, to determine various control objectives (rounded downwards from the calculated values):

- $\theta' \leq 0.10$ \j
- $X'_{0.95} \leq 130\%$ of L_{LTA}
- $G' \leq 40\%$ of L_{LTA}
- $\bar{M}' \leq 50\%$ of L_{LTA}

As before, a sophisticated sampling strategy should not be necessary to assess these objectives. A simple, efficient sampling strategy could be designed for estimating the group exceedance fraction or group 95th percentile. Alternatively, a strategy could be devised that focuses solely on the *group* mean, determined using say 6 to 10 measurements as advocated by the AIHA (Mulhausen and Damiano, 1998) for long-term mean exposure limits. Either the point estimate of the group mean

\j This is equivalent to saying that the exposure group's true 90th percentile should less than or equal to the L_{LTA}.

(when monitoring is regular and frequent) or the upper confidence limit (see Damiano and Mulhausen, 1998) would be compared to $\bar{M}'$. A superior approach may be one that assesses both central tendency and variability: the control chart approach previously mentioned could be adapted for use with a long-term average limit by plotting the sample estimates of the group 95th percentile and the group mean against their respective control objectives.

8 DUAL LIMITS

Up until recently (HSC, 2002), the United Kingdom "maximum exposure limit" for vinyl chloride was 7 ppm, using the 8-hour TWA reference period (HSE, 1999) (see Footnote b). This single shift limit was subject to an "overriding annual exposure limit of 3 ppm". The question is, can a control objective be devised that, if consistently met, will ensure compliance with both the L_{TWA} and L_{LTA}? For example, consider the following scenario. We assume as before that $D \leq 2$ and $\rho \leq 0.4$, and use the previous equations to calculate the following control objectives for L_{TWA}=7 ppm and L_{LTA}=3 ppm:

TWA	$X'_{0.95}$ = 4.40 ppm
	G' = 1.41 ppm
	$\bar{M}'$ = 1.79 ppm
LTA	$X'_{0.95}$ = 3.95 ppm
	G' = 1.26 ppm
	$\bar{M}'$ = 1.61 ppm

The control objectives calculated for the long-term average limit should be selected as the objectives as they are less than those calculated for the single-shift limit.

9 DISCUSSION

Because exposure limits are designed for the control of exposures for *each* worker, the goal of a single shift, TWA limit (or a long-term average limit) should be to control the group exposure profile such that the probability of a randomly selected worker's 95th percentile exposure (or mean exposure) exceeding the L_{TWA} (or L_{LTA}) is small, say 0.05 or less. This being the case, the ideal exposure sampling strategy would involve the repeat sampling of each worker each year such that sufficient measurements are collected to accurately estimate each worker's exposure profile. Clearly, in most instances such a strategy would be expensive and impractical. A less intensive strategy could involve repeat sampling of a limited number of randomly selected workers. However, the statistical procedures for rigorously analyzing such data relative to a TWA exposure limit have yet to be developed, and those developed for long-term average exposure limits are expensive, complex, inaccurate, and not applicable to other exposure limits.

The equations presented here can be used to devise alternative exposure management objectives. As suggested in the examples, it should be possible to evaluate compliance with these objectives using sampling strategies and decision logics that focus on the estimation of one or more parameters of the group exposure profile, such as the group 95th percentile exposure, geometric mean exposure, arithmetic mean exposure, or the group exceedance fraction. In principle, each of these parameters can estimated using a sample that consists of a single measurement from each of *n* workers. For example, the AIHA and CEN both recommend for an initial or baseline survey that six or more measurements be collected from a well defined exposure group. If the point estimate of the group exposure profile parameter is considerably less than the exposure management control objective, then there is strong evidence that the exposure profiles for at least 95% of the workers are in compliance with the exposure limit. The employer will be highly confident that this is the case whenever the upper confidence limit for the point estimate is also less than the control objective. (Additional measurements may be needed before arriving at a final decision, depending upon how close the point estimate is the control objective.)

Because random sampling is involved, the resulting data could later be used by researchers should the employer participate in an epidemiological study. On the negative side, employers may require some convincing that the corporate exposure management objective should be to control at least 95% of the exposures to $X'_{0.95}$, rather than the exposure limit L_{TWA}. But in concept, this is identical to setting an upper control limit for a critical attribute of a manufactured product so as to ensure that the vast majority of the items comply with the customer's upper specification limit.

9.1 Rules-of-thumb

9.1.1 AIHA "Critical Exposure Group" Concept

It was mentioned earlier that the AIHA uses the "critical SEG" concept to indirectly address the between-worker variability issue. The AIHA suggests that as a general rule the employer should not be overly concerned about between-worker variability whenever the sample estimate of the group 95th percentile is less than half the exposure limit. The reasoning here is that whenever the upper end of the group exposure profile is well below the exposure limit it is highly likely that all the employees are in compliance, regardless of the degree of group heterogeneity. But how useful is this rule-of-thumb?

From Figure 4 we see that for group geometric standard deviations less than approximately 3.0 this general rule results in a target control objective that is less than that calculated using Equation 11 (where $\rho \leq 0.40$). The AIHA general rule ceases to be general whenever the group geometric standard deviation exceeds 3.0 and/or the group heterogeneity coefficient exceeds 0.4. Consequently, one could conclude that for a broad range of plausible group exposure profiles the AIHA common sense, rule-of-thumb guidance was well conceived. However, if an employer has reasonably reliable information regarding the upper end of the geometric standard deviation and group heterogeneity for a specific exposure group or process, a site specific control limit can be calculated. This would be particularly advisable whenever the group geometric standard deviation or group heterogeneity coefficient are expected to exceed 3.0 and 0.4, respectively.

9.1.2 Single shift, TWA Exposure Limits

Along the same lines, the following rules-of-thumb, applicable to exposure scenarios where the group geometric standard deviation and heterogeneity coefficient are likely to be less than 3.0 and 0.4, respectively, are recommended:

- the group exceedance fraction should not exceed 0.01
- the group 95th percentile should not exceed 50% of the L_{TWA} (as recommended by the AIHA; Section 9.1.1)
- the group geometric mean should not exceed 10% of the L_{TWA}
- the group mean should not exceed 15% of the L_{TWA}.

9.1.3 Long-term Average Limits

For instances where a long-term average limit applies, and the group geometric standard deviation and heterogeneity coefficient are likely to be less than 3.0 and 0.4, respectively, the following rules-of-thumb are recommended:

- the group exceedance fraction should not exceed 0.10
- the group 95th percentile should not exceed 135% of the L_{TWA}
- the group geometric mean should not exceed 20% of the L_{TWA}
- the group mean should not exceed 40% of the L_{TWA}.

9.2 Selection of Group D and ρ

To use the equations presented here the employer must have in mind upper values for group D and ρ. These values should be reasonable upper estimates. In the previous examples, we assumed that a group D greater than 2 was unlikely. In practice, this could be determined in one of several ways. Perhaps in the employer's long experience with a particular operation or process a group D greater than 2 has rarely or never been observed. Alternatively, a statistical upper confidence limit could be calculated for a sample estimate of group D. Or a reasonable upper value could be taken from similar operations at other locations. Key to this process is that the value selected or calculated be a reasonable upper limit.

Regarding the group heterogeneity coefficient (ρ), an estimate could be directly determined or taken from the literature, such as Kromhout et al. (1993). For an operation or process that is frequently repeated throughout an industry, a trade organization should be able to develop information on group heterogeneity given different types of standard controls and work practices. A site specific, direct estimate would require the employer to collect multiple measurements from *n* employees. The resulting log-transformed dataset would then be analyzed using components-of-variance analysis techniques and a sample estimate of ρ calculated. The upper confidence limit of this sample estimate could be used as a reasonable upper estimate of ρ for purposes of calculating control objectives. In both cases, using approximate values for group D and ρ will result in *provisional* control objectives. Their suitability should be later reevaluated.

9.3 Design of Exposure Assessment Strategies

The calculation of one or more control objectives is an initial step in the design of an exposure assessment strategy. It follows from the earlier discussion on target group exceedance fractions that the TWA exposure limit should be interpreted to be at least the 99^{th} percentile of the group exposure profile. The target group 95^{th} percentile ($X'_{0.95}$) should be a fraction of the exposure limit (see Figure 4). Equation 12 can be used to calculate an upper limit for the group geometric mean. General guidance on designing a strategy where the goal is to estimate the group 95^{th} or 99^{th} percentile can be obtained from numerous sources, such as the AIHA (Mulhausen and Damiano, 1998) or CEN (1995). Readers should also consider a strategy that includes the group geometric mean. A sample estimate of the group geometric mean is inherently less variable than any other exposure profile parameter (provided the data are reasonably lognormal). For example, a strategy that estimates both the group 95^{th} percentile and geometric mean (and compares the estimates to their respective control objectives) is likely to be more sensitive to adverse changes in the group exposure profile - both variability and central tendency will be evaluated (see the later discussion on control charts).

9.3.1 General Procedure

The flowchart in Figure 11 shows the general process for designing an exposure assessment strategy using the exposure control objectives developed here.

9.3.2 Baseline Surveys

The general procedure for designing initial or baseline surveys has been discussed (Hewett, 2005b). For a baseline survey the usual presumption is that little or nothing is known about the group exposure profile. In brief, such a survey should be designed to reliably detect a poorly controlled exposure profile, if it exists. For example, we could define a "clearly unacceptable" exposure profile as one where θ_P is, for example, 0.25. Consequently, the baseline survey strategy should be designed to reliably detect a θ_P of 0.25. Verifying that a particular strategy will indeed reliably detect a clearly unacceptable θ_P requires computer simulation. Readers are referred to Hewett (2005a, 2005b) for details.

9.3.3 Infrequent or Termination/Reduction Surveys

In instances where the re-sampling interval is likely to be long, then a decision - correct or not - will be extrapolated to all employees in the group and well into the future. Consequently, the employer should be in a position to make a highly confident decision. There are times when an employer knows (e.g., when sufficient past data are available) that exposures are well-controlled or highly-controlled, and would like to reduce or terminate regular exposure monitoring. In these and similar instances the employer should calculate and compare an upper confidence limit to the control objective. In this fashion, the employer would be able to conclude with at least X% confidence that the group exposure profile is acceptable.

9.4 Control Objectives and Control Charting

In 1967, the American Conference of Governmental Industrial Hygienists (ACGIH) committee on Environmental Factors in the Pneumoconioses recommended the use of control charts for assessing exposures (Roach et al., 1967). A baseline set of 20 or more measurements should be collected. A "Warning Line" and an "Action Line" are drawn two and three standard deviations, respectively, above the mean of the baseline measurements. The Warning Line must be at or below the exposure limit. All subsequent measurements should be less than the Warning Line. Any measurement above the Warning Line should result in a "repeat visit". A second measurement above the Warning Line, or a single measurement above the Action Line indicates "…that there is good cause for immediate action to be taken to reduce the [exposures]".

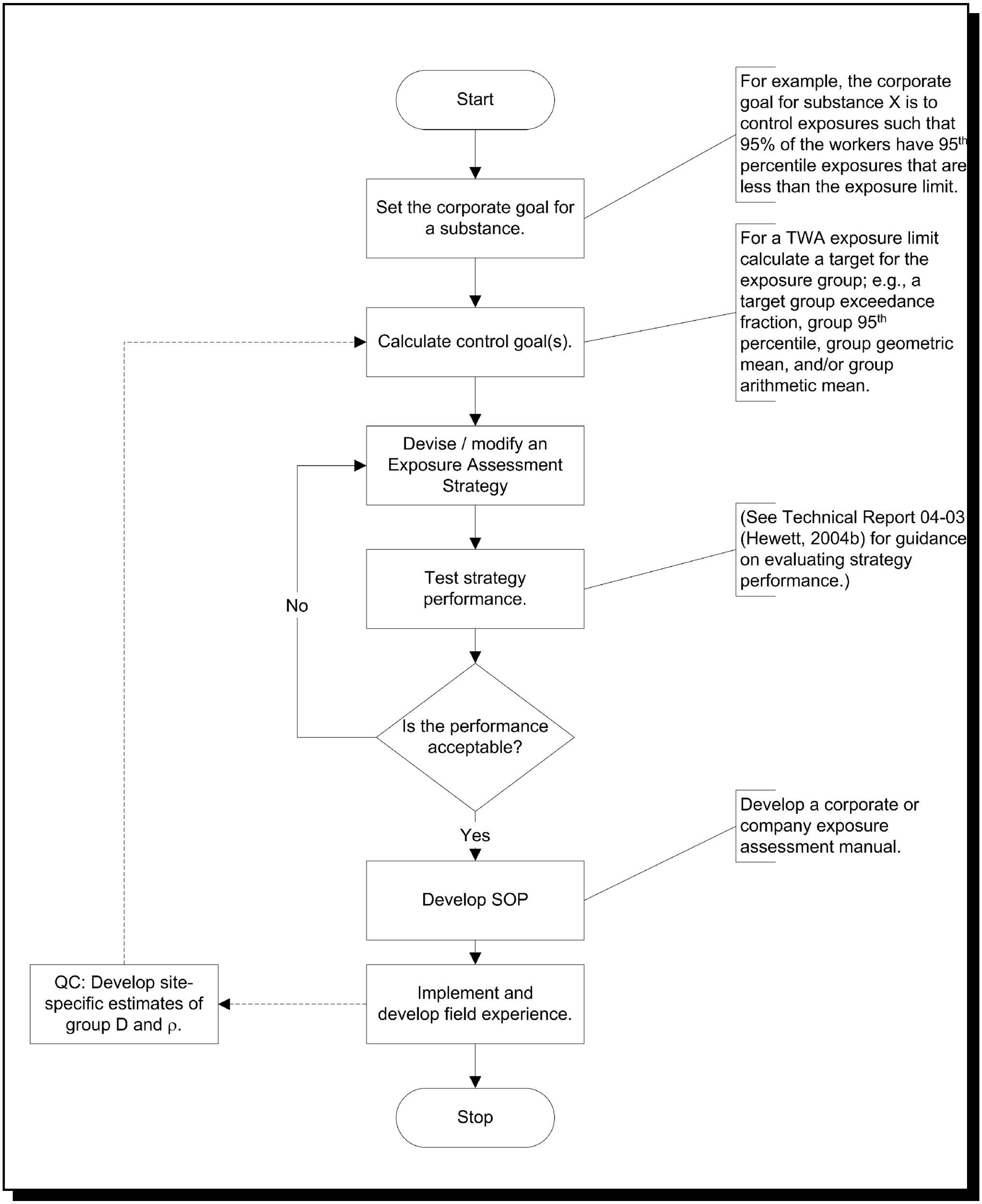

Figure 11: Generic process using control objectives to design a performance-based exposure assessment strategy.

The Action and Warning Lines correspond to the 99.9th and 97.7th percentiles for the group exposure profile. According to Roach et al., the employer should set a goal of continual improvement so that the Action and Warning Lines may eventually be moved downwards until the Action line equals the TWA exposure limit. Although at that time the ACGIH committee apparently assumed that exposures tended to be normally distributed, this approach to evaluating and controlling exposures constituted sound advice and can be applied to lognormally distributed exposures. The European Union (CEN, 1995) offered similar advice in Appendix G of their monograph on exposure assessment. Many companies use a time series plot to visualize exposure measurements collected over the past observation interval (e.g., quarter or year). Typically, two control lines are drawn: one at the TWA exposure limit and one at the Action Level (i.e., 50% of the exposure limit). In addition to the individual measurements, a company will often calculate the quarterly 95th percentile (from the sample geometric mean and geometric standard deviation) so that one can visually assess the degree of compliance for the group exposure profile.

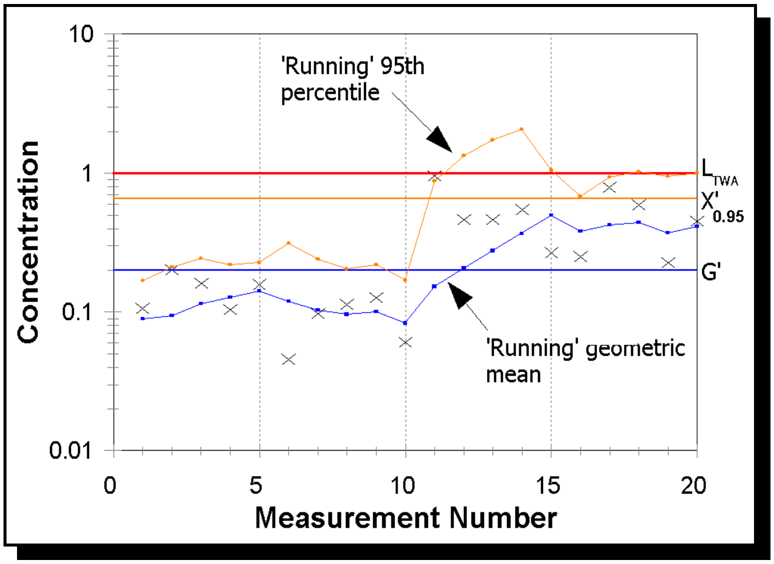

Figure 12: Example of a control chart where the control lines were fixed at the TWA exposure limit, the upper limit for the group 95th percentile (Equation 11), and the upper limit for the group geometric mean (Equation 12). Individual data points are indicated by an "X". A running group geometric mean of five measurements is indicated by the lower curve. The upper curve indicates the running group 95th percentile.

In the author's view, the control objectives recommended in this paper are suitable for calculating control lines for control charts. For example, consider the hypothetical control chart depicted in Figure 12. The TWA exposure limit is 1 ppm. The $X'_{0.95}$ and G' control lines were calculated using Equations 11 and 12, assuming that the upper limits for the group geometric standard deviation and heterogeneity coefficient are 2 and 0.4, respectively (as was assumed in previous examples). According to Figure 2, no more than 1% of the group exposures should exceed the exposure limit. Since the TWA exposure limit should be considered the 99th percentile exposure for the group exposure profile, any measurement above L_{TWA} should result in an investigation. This is consistent with guidance published by several organizations. \[k] The $X'_{0.95}$ and G' lines are the upper limits for the group 95th percentile and geometric mean, respectively. A moving (group) geometric mean is indicated by the lower curve, while the upper curve indicates a moving (group) 95th percentile. Both were calculated using the most recent five measurements.

From measurements #1 to #10, both the moving geometric mean and 95th percentile were less than their respective control lines. Therefore, over this interval the employer had *continual assurance that at least 95% of the employees* had individual 95th percentiles that were less than the exposure limit. Between measurements #10 and #11 a process change occurred, resulting in an increase in both the true, but unknown, group geometric mean and geometric standard deviation. By measurement #12 both the moving geometric mean and 95th percentile had exceeded their respective control lines. Although all measurements were less than the exposure limit, the employer should have concluded at measurement #12 that it was possible that *less than* 95% of the employees had acceptable exposure profiles, and launched an investigation into the determinants of exposure. Other types of control charts can be envisioned, but the above should suggest how control objectives could be used in a practical sense.

\[k] The AIHA (Mulhausen and Damiano, 1998) suggested that each over-exposure be investigated. In the ASTM standard on crystalline silica it is recommended that all unexplained over-exposures result in a "root cause" investigation (ASTM, 1999). OSHA requires an investigation and appropriate action if any single measurement exceeds the Permissible Exposure Limit. In the United Kingdom, the Health and Safety Executive requires "measures to reduce exposure" whenever any single measurement exceeds the limit (HSE, 1999).

10 CONCLUSIONS

Equations were presented that permit the calculation of exposure management objectives for single shift, TWA exposure limits, long-term average exposure limits, and dual limits (where both a single shift and long-term limit apply). If these objectives are met, then it can be inferred that the fraction of workers with 95^{th} percentile exposures exceeding the single shift limit (or mean exposures exceeding the long-term limit) is also controlled to a target value. One rule-of-thumb that results from this analysis is that the traditional single shift, TWA exposure limits should be interpreted statistically as the 99^{th} percentile exposure, rather than the 95^{th} percentile exposure as is recommended by various organizations and authorities.

In principle, these control objectives can be evaluated using the simple, common sense exposure sampling strategies and data analysis schemes advocated by the AIHA (Mulhausen and Damiano, 1995) and the European Union (CEN, 1995).

Although the focus has been on exposure limits for gases, vapors, and particulates, it is expected that these concepts apply to exposures limits for physical hazards as well. The author welcomes any comments or observations regarding the concepts and recommendations presented in this report.

11 ACKNOWLEDGMENTS

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