PERFORMANCE-BASED EXPOSURE ASSESSMENT STRATEGIES FOR TWA EXPOSURE LIMITS

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1 ABSTRACT

A procedure is proposed for designing a performance-based "exposure assessment" strategy; that is, a strategy that is both effective (i.e., the strategy will reliably achieve a specific objective), and efficient (i.e., the strategy requires a minimum or tolerable expenditure of program resources). The objective addressed in this paper is the detection of an unacceptable group exposure profile during a baseline exposure assessment survey, although the design of a termination/reduction strategy is addressed. The strategy "performance curve" (i.e., operating characteristic curve) is used as the primary instrument for comparing the effectiveness of different strategies. The strategy "sample size" curve, is used to evaluate the efficiency of the sampling strategy.

Computer simulation was used to estimate the performance and sample size curves for five off-the-shelf exposure assessment strategies. Two strategies - the OSHA Inspector strategy and the OSHA-NIOSH strategy (used in the OSHA 6b standards) - are highly efficient; that is, a decision can be reached on the basis of just a few measurements. But neither are very effective; they do not have sufficient power to reliably detect poorly controlled group exposure profiles. Consequently, neither is suitable for baseline exposure assessments, but with modification their performance can be improved. The default versions of the AIHA "Similar Exposure Group" strategy and a similar two-stage corporate strategy are both effective at detecting poorly controlled exposure profiles. Computer simulation showed that modest changes in the corporate strategy will result in a substantial improvement in efficiency, without compromising its effectiveness. Similar changes could be applied to the AIHA strategy. The fifth strategy was taken from guidance on exposure assessment published by the European Union. Decisions are made with great efficiency, but computer simulation revealed that it was not sufficiently effective. A simple change to the strategy improved the effectiveness without changing strategy efficiency.

In summary, the author suggests that strategies for baseline exposure assessments be purposefully designed to reliably detect poorly-controlled exposure profiles. As demonstrated in this paper, computer simulation can be a valuable tool when designing true, performance-based exposure assessment strategies.

2 INTRODUCTION

Industrial hygienists have been cautioned to regularly evaluate the work environment and compare exposure measurements against occupational exposure limits (OEL) (Corn, 1988; CEN, 1995; HSE, 1999; Mulhausen and Damiano, 1998). Such evaluations require that a "sampling strategy" be devised for the collection, (statistical) analysis, and interpretation of exposure data (relative to an OEL). Given the usual limited resources provided by most employers, industrial hygienists are often compelled to design sampling strategies aimed at satisfying the minimum requirements for exposure assessment that exist in the regulatory codes of most nations. Such minimalistic strategies are often incapable of reliably detecting poorly controlled exposures (Tuggle, 1981; OSHA, 2003a). In general, any strategy that requires only a small number of measurements may lead to an incorrect decision that the entire distribution of exposures for the exposure group in question is acceptable. This incorrect decision may then be extrapolated to other workers and well into the future. Consequently, the sampling strategy for a baseline (i.e., initial) exposure assessment should be designed so that there is a high probability of detecting a clearly unacceptable group exposure profile.

The purpose of this paper is to propose a procedure for designing a performance-based exposure assessment strategy (hereafter referred to as a performance-based strategy), which is here defined as a strategy for assessing workplace exposures that is designed to reliably achieve a specific objective.[a] For this paper, that objective is assumed to be the detection of unacceptable exposure profiles (i.e., work environments) during baseline exposure surveys (Hewett, 1999, 2003). To demonstrate the utility of this procedure, several regulatory and published sampling strategies are evaluated and critiqued. In each case, it is shown that relatively minor changes can substantially improve strategy performance. Readers are encouraged to evaluate their own strategies in a similar manner. Towards this end, a conceptual model for group exposure exposures is provided (see Appendix A), as well as guidance on using this model to generate random exposures (Appendix B).

3 GLOSSARY

acceptable exposure profile - an exposure profile that can be reasonably described as "in control"; an exposure profile where the *true* exceedance fraction (θ) is less than or equal to a generally accepted value (e.g., $\theta \leq 0.05$); an exposure profile where the true 95th percentile is less than or equal to the exposure limit (or other criterion; e.g., action limit).

baseline survey - an exposure assessment survey for a work environment (a) that has never before been evaluated relative to a particular exposure limit, or (b) where the process has changed significantly since the last evaluation; the "initial survey" survey referred to in many OSHA regulations.

clearly unacceptable exposure profile - an exposure profile where nearly all concerned would agree that the exceedance fraction is unacceptable (e.g., an exposure profile where $\theta \geq 0.25$).

clearly acceptable exposure profile - an exposure profile where nearly all concerned would agree that the exceedance fraction is acceptable (e.g., an exposure profile where $\theta \leq 0.01$).

effectiveness - the ability to reach a correct decision; e.g., the power of an exposure assessment strategy to detect a clearly unacceptable (or clearly acceptable) exposure profile.

efficiency - the ability of an exposure assessment strategy to reach a decision with a minimum or tolerable expenditure of resources; e.g., the number of exposure measurements on average per survey, or the total cost in terms of personnel, travel, analytical fees, and other expenses.

Employees' Risk - the likelihood that a clearly unacceptable exposure profile is declared acceptable. For a baseline survey, this is similar to the "consumers' risk" concept used in quality control; also known as Type II error or β-error; the probability of a false negative exposure assessment.

Employer's Risk - the likelihood that a clearly acceptable exposure profile is declared unacceptable. For a baseline survey, this is similar to the "producer's risk" concept used in quality control; also known as Type I error or α-error; the probability of a false positive exposure assessment.

exceedance fraction - θ (theta), the fraction of full-shift, time weighted average (TWA) exposures that exceeds the exposure limit; the fraction of an exposure profile that exceeds the exposure limit.

exposure profile - the current distribution (i.e., probability density function) of exposures for a worker, or a group of workers that have been aggregated by similarity of work environment and work conditions. Typically this distribution is well described using the lognormal distribution model.

power - for baseline surveys, the probability of detecting a clearly unacceptable exposure profile, calculated as 1-Employees'

[a] The minimum strategies found in the government regulations are sometimes referred to as specification-based or prescriptive strategies, in that they specify the number of measurements to be collected, the time frame for collection, and the rules for interpreting the measurements relative to the exposure limit. However, there is nothing that prevents an employer from improving upon these strategies.

Risk; for termination/reduction surveys the probability of detecting a clearly acceptable exposure profile, calculated as 1-Employer's Risk.

termination/reduction survey - an exposure assessment survey where the group exposure profile is felt to be well-controlled or highly-controlled, but compelling (exposure) evidence is needed before terminating or reducing regular monitoring, before removing employees from a medical surveillance program or hearing conservation program, before removing employees from a respiratory PPE program, or some other similar action.

unacceptable exposure profile - an exposure profile that can be reasonably described as poorly controlled or uncontrolled (e.g., an exposure profile where θ>0.05).

4 BACKGROUND

In 1981, Tuggle analyzed the recently published NIOSH exposure sampling strategy (Leidel, Busch, and Lynch, 1977). He estimated the performance curves for the 1977 NIOSH exposure sampling strategy using a Markov chain calculation procedure and showed that the NIOSH strategy was unlikely to detect clearly unacceptable worker exposure profiles, relative to single shift, TWA exposure limits. For example, in Figure 1 his Figure 3 is reproduced. The x-axis represents the exceedance fraction for a particular worker. The y-axis represents the probability of deciding that exposures are acceptable. Let us assume, as he did, that a worker has an exposure profile with a geometric standard deviation of 2.0. At an exceedance fraction of 0.25 (i.e., one out of four exposures exceeds the exposure limit) Tuggle predicted that use of the NIOSH strategy will result in the wrong decision more than 50% of the time.\[b] This strategy, with minor variations, has since been incorporated into numerous Occupational Safety and Health Administration (OSHA) single substance standards, and is often used for doing the initial survey required by the U.S. regulations. The question before us is, can this strategy be improved to where it is truly suitable for baseline surveys?

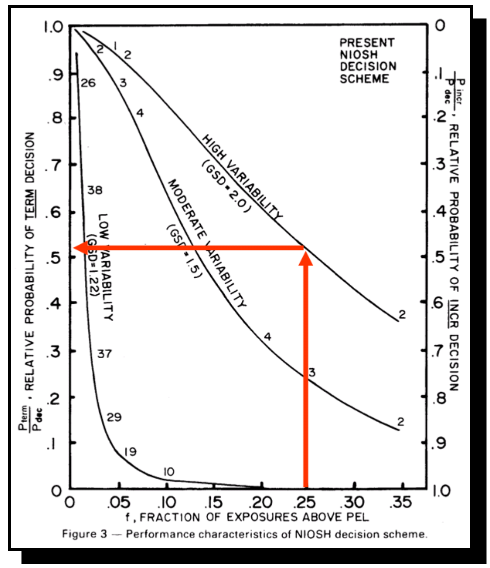

Figure 1: Figure 3 from Tuggle (1981) in which he showed that the NIOSH 1977 strategy was likely to result in an incorrect decision more than 50% of the time whenever the true fraction of over-exposures was a clearly unacceptable 25%. [arrows added for emphasis]

The exposure management <u>goal</u> inherent in all exposure limits is the effective and continuous control of *each* worker's exposure profile. This goal is achieved by meeting both exposure assessment <u>objectives</u> and exposure control objectives. The sole objective of many company and corporate exposure assessment surveys is to simply demonstrate minimal compliance with OSHA regulations. During what OSHA calls "initial exposure monitoring" the employer often collects the minimum number of measurements and applies the least rigorous decision scheme permitted by the regulations (which almost always is a simple comparison of each measurement to the limit). In this paper, the focus is on the design of strategies that go beyond the minimum OSHA requirements, and reliably detect poorly controlled work environments. At this point, an exposure parameter is needed that is deemed relevant for assessing compliance with an exposure limit.

4.1 Establish an Objective for Baseline Surveys

This paper focuses on strategies designed for evaluating compliance with single-shift, TWA limits. The overwhelming majority of such exposure limits for gases, vapors, and particulates - whether they are regulatory, consensus, or corporate limits - have as their implicit or explicit goal the control of exposures for *each* exposed employee such that there are few,

\[b] To be fair, the NIOSH 1977 strategy was not intended for baseline surveys of poorly controlled work environments. It was designed to permit an employer with an already controlled work environment to quickly and efficiently demonstrate compliance.

if any, overexposures (Hewett, 1996, 2001a, 2001b). It follows that the goal of an employer's exposure management program should be to ensure, through a mixture of exposure assessment and exposure control, that very few workers have upper percentile exposures greater than the exposure limit. Consequently, for a typical exposure limit an appropriate measure of compliance would be the *probability* that a randomly selected worker's "95th percentile exposure" is greater than the exposure limit. However, to date, there are no published exposure assessment strategies that directly estimate this probability.\[c] The nearly universal approach is to devise exposure groups that are reasonably homogeneous with respect to the substance, controls, job/tasks, and work practices, and evaluate the *group* 95th percentile or the group exceedance fraction (Corn and Esmen, 1979; Still and Wells, 1989; CEN, 1995; Mulhausen and Damiano, 1998). Consequently, for the purpose of introducing the concept of performance-based strategies we shall assume that one of the objectives of an exposure assessment program is the detection of exposure groups where the "group exceedance fraction" is clearly unacceptable.

4.2 Employer Obligations

OSHA (1988) indicated that it was interested in developing a generic exposure assessment strategy that would, with perhaps minor modifications in each case, be applied to all OSHA Permissible Exposure Limits (PELs) without substance specific strategy requirements (i.e., the so-called Z-table PELs). OSHA anticipated that this strategy would be performance-based, implying that performance goals would be specified, but that a company would have considerable latitude when designing a site-specific strategy. This proposal elicited considerable interest and comment. For example, the American Industrial Hygiene Association (AIHA, 1997) published the following position statement in 1994:

> "... A performance oriented approach to a GEAS [i.e., generic exposure assessment standard] will encourage innovative and effective [exposure] assessments, ... and ensure that limited resources are most efficiently utilized to recognize, evaluate, and control hazardous workplace exposures. ..."

However, OSHA did not follow-up with a generic exposure assessment standard. Nonetheless, OSHA (2003b) has repeatedly indicated that it expects employers to design an effective strategy. For example:

> "Unless the employer chooses to measure the exposure of each employee potentially exposed to formaldehyde, the employer shall develop a representative sampling strategy and measure sufficient exposures within each job classification for each workshift to *correctly characterize and not underestimate* [emphasis added] the exposure of any employee within each exposure group." (29 CFR 1910.1048(d)(2)(i))

Furthermore, OSHA expects that the exposure profile of each worker be controlled such that there are few overexposures. For example, regarding exposure to asbestos OSHA (1986) stated the following:

> "OSHA believes, however, that an employer's demonstration that an inspector's one-day sample is unrepresentative, in most cases, should consist of a series of full-shift measurements of the exposure of the employee under consideration. These measurements should consist of all valid measurements of the employee under consideration taken within the last year and should show that on *relatively rare occasions* [emphasis added] could random fluctuations result in measurement TWA concentrations above the PEL."

Along similar lines, the U.S. Department of Energy (DOE, 1999) published a final rule regarding prevention programs for chronic beryllium disease. The rule contains the following provisions:

> "The responsible employer [i.e., DOE contractor] must apply statistically-based monitoring strategies to obtain a sufficient number of samples *to adequately characterize exposures, before reducing or terminating monitoring* [emphasis added] ... [and] ... must conduct periodic monitoring of workers who work in areas where airborne concentrations of beryllium are at or above the action level [i.e., 10% of the

\[c] It is possible to estimate the probability that a randomly selected worker's 95th percentile exposure exceeds the TWA exposure limit, but this requires that many or all of the workers be sampled repeatedly. The data are then analyzed using components of variance techniques. See EAS Inc. Technical Report 05-01 (Hewett, 2005a) for more details.

PEL]. The monitoring must be conducted in a manner and at a frequency necessary to represent workers' exposure ... [or] ... at least every 3 months."

So, how does an employer design a strategy that will "correctly characterize and not underestimate" (OSHA, 2003b) both individual and exposure group exposure profiles, or "adequately characterize exposures before reducing or terminating monitoring" (DOE, 1999)?

5 DESIGN PROCEDURE FOR PERFORMANCE-BASED STRATEGIES

An eight step process (see Figure 2) is proposed for determining whether a particular exposure assessment strategy is sufficiently effective and efficient for baseline surveys (or termination/reduction surveys):

1. state the hypotheses to be tested
2. define acceptable and clearly unacceptable (or clearly acceptable) exposure profiles
3. specify the *target* Employees' Risk (or Employers' Risk)
4. specify the components of the proposed or existing strategy
5. estimate the actual Employees' Risk (or Employer's Risk)
6. compare the estimated risk and target risk
7. modify (go to step 5) or reject (go to step 4) the proposed strategy
8. implement (and periodically reassess)

5.1 State the hypotheses to be tested

In the context of group exceedance fractions, the hypotheses to be tested are:

H_o: $\theta = \theta_1$ (acceptable exposure profile)
H_a: $\theta > \theta_1$ (unacceptable exposure profile)

This formulation is consistent with the literal interpretation of single shift exposure limits as upper limits on exposures (Corn and Esmen, 1979; CEN, 1995; Mulhausen and Damiano, 1998; Hewett, 1996, 2001a, 2001b). The question being asked is this: Is there sufficient or compelling evidence that the true θ for the exposure group is greater than θ_1.

5.2 Define "acceptable", "clearly unacceptable", and "clearly acceptable" exposure profiles

Using the conventions of various groups (CEN, 1995; HSE, 1999; Mulhausen and Damiano, 1998) and authorities (Corn and Esmen, 1979; Still and Wells, 1989) an acceptable exposure profile is defined as one where θ=0.05. Consequently, the null hypothesis θ_1 is set at 0.05. For the sake of discussion, a clearly unacceptable group exceedance fraction (θ_2) is set at 0.25. For termination/reduction strategies (discussed in more detail later and in Appendix A), a clearly acceptable θ_2 could be set at 0.01, for example.

5.3 Specify the *target* Employees' Risk

This is a critical step in the design process. The employer must specify a target value for the decision error that corresponds to θ_2. To demonstrate this procedure, well established conventions in the field of statistical process control were followed. For a baseline survey the employer should design a strategy where the probability of falsely concluding that the exposure profile is *acceptable* - i.e., Employees' Risk - is no more than 0.10 whenever θ_2=0.25. Another way of looking at it is that the target power of the strategy to detect a clearly unacceptable exposure profile when $\theta = \theta_2$ should be at least 0.90, or 1-Employees' Risk.

5.4 Specify the components of the proposed or existing strategy

An exposure assessment strategy consists of criteria for selecting workers and sample days, a statistical analysis of exposure data, and a decision logic for interpreting the data (or statistics) (Hewett, 2001a). These components will already be established whenever an off-the-shelf strategy is used, such as the AIHA "Similar Exposure Group" (SEG) strategy (Mulhausen and Damiano, 1998). The strategy decision logic may consist of a formal statistical test, a set of predetermined rules for classifying each exposure measurement, or a combination of both.

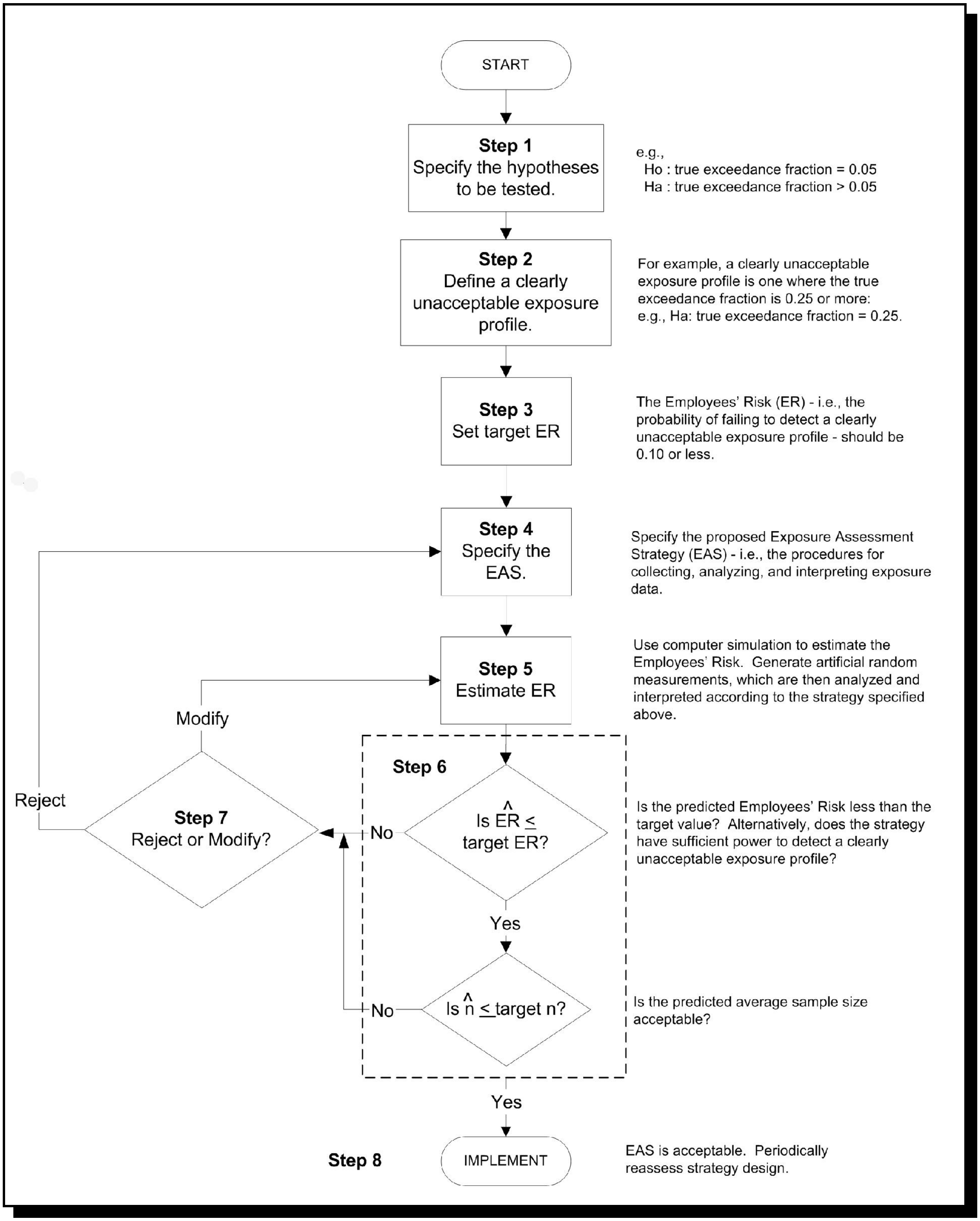

Figure 2: General procedure for designing a performance-based exposure strategy.

5.5 Estimate the actual Employees' Risk (or Employer's Risk)

The Employees' Risk (or Employer's Risk) for any particular strategy configuration can be estimated either by computer simulation (discussed later) or direct calculation (which is possible only with the simplest of sampling strategies). The computer simulation results can be displayed using a performance curve such as that in Figure 3A (the thick line). The performance curve indicates the probability of *deciding* that the exposure profile is acceptable.

In addition to the performance curve, it is possible to estimate and display a sample size curve, which we will interpret as an efficiency curve. For example, in Figure 3A the graph has a thin line curve that is read against the right y-axis. This curve indicates the number of measurements, on average, required to reach a decision. This average sample size can be regarded as a surrogate for the total program resources required. Evaluation of both curves permits an assessment of the effectiveness and efficiency of the sampling strategy.

5.6 Compare the estimated risk and target risk

Figure 3A shows the performance and efficiency curves for the OSHA-NIOSH strategy. At θ=0.25 the probability of declaring the exposure profile acceptable is approximately equal to 0.58, considerably more that the target value of 0.10. Consequently, the power to detect a clearly unacceptable group exceedance fraction is a low 0.42.

5.7 Modify or reject the proposed strategy

The strategy should be modified (or rejected) if the estimated Employees' Risk is greater than 0.10 or the sample size is larger than desired. Depending upon the type of strategy, modification may consist of adjusting the sample size or making the decision rules more stringent. Before rejecting a particular strategy one should consider both its advantages and disadvantages. Perhaps it has the advantage of simplicity and ease of use. For example, assuming roughly equal performance curves, an exposure assessment strategy based upon simple decision rules, in the long run, might be easier to implement and more effective in practice than a more complicated strategy.

5.8 Implement

If the estimated Employees' Risk is less than 0.10, and the estimated sample size is acceptable, then one can stop. The strategy performs as desired, and at a tolerable level of efficiency. The strategy could be considered both defensible, in that it was designed through a logical process, and ethical, in that it was designed to reliably detect clearly unacceptable exposure profiles (if present). Given that the predicted performance is only as good as the assumptions used in the simulation, the strategy performance should be re-evaluated whenever improved information on the group exposure profile parameters (discussed in the next section and in Appendices A and B) becomes available.

6 COMPUTER SIMULATION

In addition to Tuggle (1981), Bowman, Busch, and Shulman (1983) used computer simulation to estimate and compare the expected performance of several proposed sampling strategies (for use in the mining industries) to monitor exposures relative to a single shift, TWA exposure limit. Others (Lyles, Kupper, and Rappaport, 1996; Lyles and Kupper, 1996) have used computer simulation to estimate the performance of particular strategies for assessing compliance with a true, long-term average exposure limit - a rarely encountered type of exposure limit (Hewett, 2001). Because none of the above authors published their conceptual model and equations for generating random exposures and testing strategies, a brief overview is provided here. Readers should note that it is possible to develop a computer simulation of a specific sampling strategy using a variety of computer programs, including most computer spreadsheets. The basic steps are:

- generate random exposures
- analyze the (artificial) measurements using the procedures specified by the strategy, and
- interpret the results relative to a TWA exposure limit.

It is not the purpose of this paper to show how to do computer simulation, but briefly the process is as follows. First, a conceptual model is needed for mathematically describing worker and group exposure profiles. One such model is presented in Appendix A and in Hewett (2005a). Next, a relevant exposure parameter should be selected. For example, let us select the group exceedance fraction and pick a clearly unacceptable value of θ=0.25 (i.e., 25% overexposures). For a fixed geometric standard deviation (D) and level of group heterogeneity (discussed in Appendix A), the corresponding group geometric mean (G) can be calculated (see Appendix B) as well as the within- and between-worker geometric standard deviations (using a components-of-variance model for log-transformed exposures). The group geometric mean and the between-worker D are then used to computer generate a geometric mean for the exposure profile of a randomly selected worker. This worker-specific G is paired with the within-worker D to generate a random exposure. This process is repeated for as many workers (or measurements per worker) as are necessary for each survey. The artificial data are then analyzed and interpreted according to the specified strategy. Such artificial exposure assessment surveys are then repeated hundreds to thousands of times.\[d] Counter variables are used to keep track of the number of artificial surveys that lead to a decision that the exposure profile was acceptable. This entire procedure can be repeated for a range of group exceedance fractions (θ), thus permitting the graphing of both the performance curve and the average sample size curve, as in Figures 3 through 12.

7 CRITIQUE OF SELECTED STRATEGIES

To demonstrate the process and utility of computer aided design, several strategies typical of the types of exposure assessment programs encountered in industry were selected for analysis:

- OSHA-NIOSH 6b strategy
- OSHA Inspector strategy
- AIHA SEG (i.e., Similar Exposure Group) strategy
- Alcoa / Damiano HEG (i.e., Homogeneous Exposure Group) strategy
- CEN "HEG" strategy.

Each of these strategies are discussed below and outlined in Appendix C. To illustrate strategy design through computer simulation the author developed a freeware program which can be obtained at www.oesh.com. This program permits the estimation of the performance curves for all of the above strategies.

With the exception of the OSHA Z-table strategy, each strategy has a default, or recommended, configuration. But in fact, hundreds to thousands of variations are possible with each strategy, and each variation will have a unique performance curve. The selected strategies were critiqued on the following questions:

- What is the Employees' Risk when the true exposure profile is clearly unacceptable?
- Are modifications necessary to achieve the target Employees' Risk?
- How many measurements, on average, are necessary to reliably detect a clearly unacceptable exposure profile?

If necessary, the strategies were modified to improve strategy performance or to increase the strategy efficiency.

We previously specified the null and alternative hypotheses, defined clearly unacceptable, and picked a target Employees' Risk. For each of the above strategies, we will specify the components of the strategy, estimate (using computer simulation) the Employees' Risk when exposures are clearly unacceptable, compare the estimated risk to the target risk, and modify the strategy until it is acceptable for doing baseline surveys. Since it is not possible to comment on all aspects of each strategy, or to contrast the strategies on all possible permutations of sample size, group heterogeneity and geometric standard deviation (D), and so on, the focus will be on the default configuration for each strategy, using only one group D and one level of group heterogeneity. The group D will be set at 2.5, which Kromhout, Symanski, and Rappaport (1993) found was a median group D for various industries. The group heterogeneity coefficient (ρ) (see Appendix A), which is the ratio of

\[d] For this paper 10000 simulations were done for each increment of the performance curve x-axis.

the between-worker variability to the group total variability (using log-transformed exposure measurements), will be set at 0.20, which in the same study was the median value observed. These values were selected for demonstration purposes only.

7.1 OSHA-NIOSH 6b strategy

The OSHA-NIOSH strategy was developed to assist employers to efficiently demonstrate compliance with the Z-table PELs (Leidel, Busch, and Lynch, 1977). As Tuggle (1981) demonstrated (see Section 4), that efficiency comes at a price. He concluded that this strategy would not reliably detect poorly controlled work environments. However, OSHA has incorporated this strategy, with minor variations, into more than a dozen OSHA 6b (i.e., individual substance) standards as the minimum level effort required of the employer. Consequently, it is often used by employers for the "initial" exposure assessment required by the OSHA 6b standards. The employer is permitted to declare the exposure profile acceptable if either the first or any two measurements in a row are less than the Action Limit (AL; typically defined as 50% of the OEL). The employer is also encouraged to select employees who routinely experience higher exposures (i.e., the so-called "most exposed" or "maximum risk" employees). For this paper, the default configuration is assumed to require that measurements are obtained from a single, randomly selected worker.

7.1.1 Efficiency and effectiveness

The default configuration results in an Employees' Risk of 0.58 (see Figure 3A). That is, this strategy has a power of only 0.42 to detect θ=0.25. On the positive side, fewer than two measurements on average are required to reach a decision. Because the power of the strategy to detect a clearly unacceptable group exposure profile is much greater than the target value of 0.10, the strategy should either be modified or replaced with a superior strategy. If we increase the number of randomly selected workers to 5 the power increases to approximately 0.90. Because each worker may be sampled more than once under this strategy, approximately 6 measurements on average will be required to reach a decision (Figure 3B). Other options could be explored. For example, a simulation can be designed to evaluate the use of professional judgment when selecting the most exposed workers. For example, if the industrial hygienist can reliably select workers having median exposures in the top 50% of the group, then only three workers need be sampled in order to attain a power of 0.90, and on average only 3.5 measurements are necessary (Figure 3C).

7.1.2 Comments

Variations on the OSHA-NIOSH strategy have been incorporated into numerous OSHA 6b standards as the minimal strategy to use when conducting an initial exposure assessment. This is interesting, because it was never designed for baseline or initial exposure surveys and had early on been shown to be ineffective at detecting poorly controlled exposure profiles (Tuggle, 1981). Nonetheless, as shown earlier it can be modified so that it has a suitable performance curve. Modification involves the collection of additional measurements, but that is the necessary additional burden if an employer insists on using the OSHA-NIOSH strategy and at the same time is serious about detecting poorly controlled work environments during initial and baseline surveys.

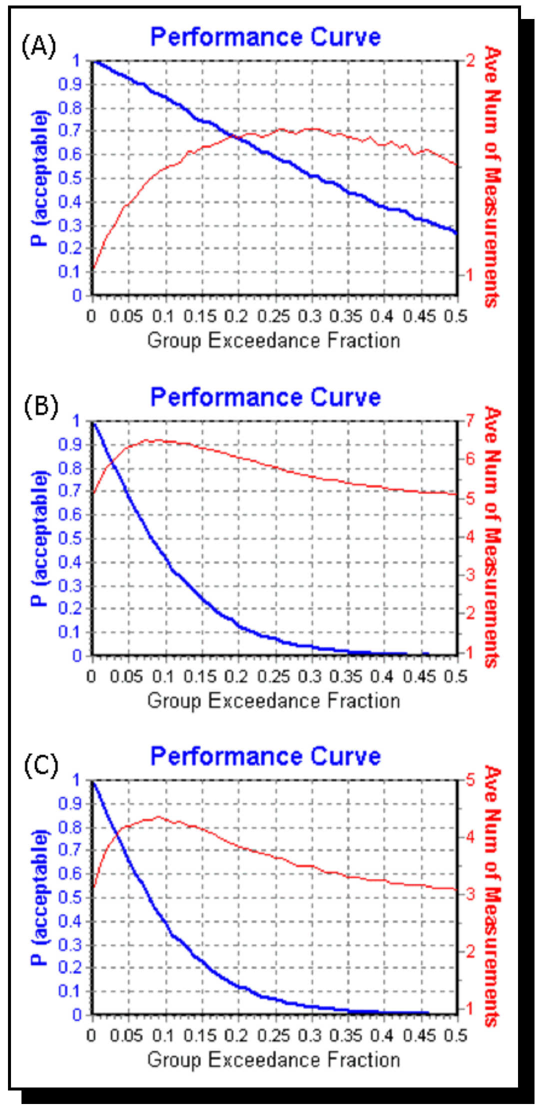

Figure 3: Predicted performance and sample size curves for the OSHA-NIOSH strategy for three scenarios: (A) a single measurement is collected from a single worker, (B) five workers are selected for sampling, and (C) three workers are selected whose exposures are routinely in the top 50%.

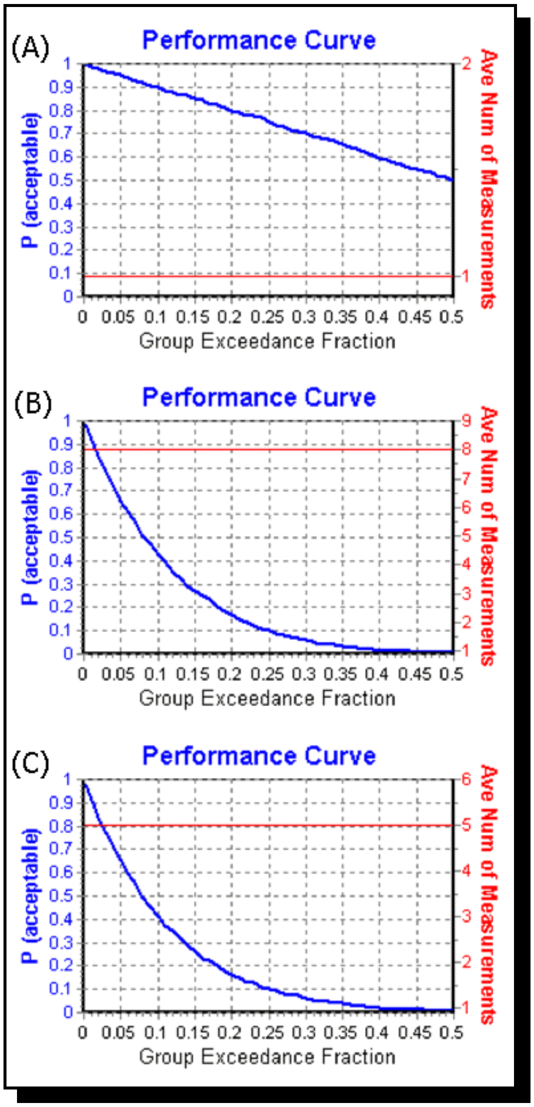

Figure 4: Predicted performance and sample size curves for the OSHA Inspector strategy for three scenarios: (A) a measurement is collected from a single worker, (B) a measurement is collected from each of eight workers, and (C) a measurement is collected each of five workers whose exposures are routinely in the top 50%.

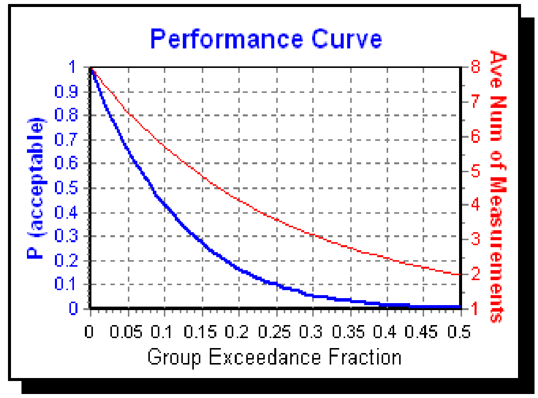

Figure 5: Predicted performance and sample size curve for the OSHA Inspector strategy for the scenario where a measurement is sequentially (e.g., one per month) collected from each of eight workers.

7.2 OSHA Inspector strategy

OSHA (2003b) stated that each full-shift, TWA exposure should not exceed the PELs listed in the various Z-tables of 29 CFR 1910.1000. For the sake of discussion, this type of strategy - the simple comparison of each measurement to the OEL - will be referred to as the OSHA Inspector strategy. Because OSHA specified no minimum sample size for Z-table substances, we will set the default sample size to n=1.

7.2.1 Efficiency and Effectiveness

If an employer adopts an OSHA Inspector type strategy, the Employees' Risk whenever θ=0.25 is 0.75 for *n=1* (see Figure 4A).[e] The sample size must be 8 or more for the Employees' Risk to decrease to 0.10 or less (Figure 4B). Employers are encouraged in many of the OSHA single substance regulations to select the maximum risk employees (often referred to in the regulations as the "representative worker"). If professional judgment can be used to reliably select the higher exposed workers (defined in Section 7.1.1), the same result can be achieved, but with a reduced sample size of 5 (Figure 4C).

7.2.2 Comments

Many employers have adopted the OSHA Inspector strategy; that is, the collection of a limited set of measurements and the simple comparison of each measurement to the exposure limit. If the sample size is sufficient and/or the employer can reliably select those employees that routinely experience the higher exposure, then computer simulation shows that this strategy can perform as well as the other strategies discussed in this report. A considerable number of variations on this strategy are possible. For example, let us assume that measurements will be collected sequentially, say one per month, rather than campaign fashion where all are collected during one or two days. In this scenario the performance curve will not

[e] The basic performance curve for an inspector-type strategy is easily calculated: P(acceptable)=$(1-\theta)^n$. However, computer simulation is required whenever the strategy is made more complex; for example, by adding the use of professional judgment for the selection of the higher exposed workers.

change, but the efficiency curve changes dramatically. For example, consider the performance and efficiency curves in Figure 5. Here the target sample size is n=8, but the measurements are collected sequentially, say one per month. When θ=0.25 and sequential collection is used only 3.5 measurements are needed, *on average*, before a measurement exceeds the limit. This suggests that a simple, easy to implement inspector type strategy can be designed that is both effective and efficient (at least at high values of θ).

7.3 AIHA 'SEG' strategy

The AIHA SEG strategy (Mulhausen and Damiano, 1998), which was first recommended in 1991 (Hawkins, Norwood, and Rock, 1991), is a well known strategy with a pedigree (Corn and Esmen, 1979) going back several decades. This strategy was based on the notion that the employer should attempt to characterize the central location and spread of the exposure profile of a SEG, and then estimate the upper percentile exposure (e.g., the 95th percentile) for the group. The SEG is defined as a group of workers aggregated by similarity of job, task, area, and substance. The SEG exposure profile is provisionally acceptable if the point estimate of the upper percentile is considerably less than the exposure limit.\[f] The AIHA suggested that 6 to 10 measurements are usually sufficient for a baseline assessment, but did not evaluate the ability of such a strategy to detect poorly controlled work environments. The default configuration of this strategy is assumed to be the collection of 6 measurements and the estimation of the group 95th percentile.

7.3.1 Efficiency and Effectiveness

The performance curve for the AIHA SEG strategy, using the default configuration, results in a respectable performance curve (see Figure 6A). When θ=0.25 and $n=6$ the power is around 0.90. As the sample size increases, the power increases. For n=10, the power is 0.98, making it virtually certain that θ=0.25 will be detected (Figure 6B). Figure 6C shows that reducing the sample size to 5 workers does not significantly change the performance curve, while reducing the number of measurements by 17%.

7.3.2 Comments

The AIHA "SEG" strategy is effective at detecting poorly-controlled exposure profiles, as we have defined them in this paper. However, there is room for improvement. The strategy could be modified into a two-stage strategy similar to that of the modified Alcoa/Damiano strategy (Section 7.4) or the CEN "HEG" strategy (Section 7.5), to result in a more efficient approach to exposure assessment.

7.4 Alcoa / Damiano 'HEG' strategy

In 1995, Damiano published the two-stage sampling strategy used by Alcoa during the early 1990s. This strategy was patterned after the 1991 version of the AIHA strategy (Hawkins, Norwood, and Rock, 1991), but was divided into two stages and coupled with sensitizing rules (see Appendix C) designed to encourage a quick, efficient decision at the first stage whenever exposures are either well-controlled or poorly-controlled. In practice, however, Alcoa found that rarely was a decision made at the first stage. Extra measurements were almost always required. The default configuration of this strategy is assumed to be the initial collection of an exposure measurement from each of five randomly selected workers. If neither of the sensitizing rules are triggered, then three additional measurements are collected. The default exposure parameter estimated from the data is the group 95th percentile.

7.4.1 Efficiency and Effectiveness

The performance curve for this strategy, using the default configuration, results in a performance curve (see Figure 7A) that is slightly more stringent than the default AIHA strategy performance curve (Figure 6A). The efficiency curve (see Figure 7A) predicts that the average sample size approaches 5 (the Stage 1 sample size) whenever θ is less than 0.02, but is 7 or greater for θ between 0.10 and 0.50. This suggests that the strategy performs as intended for very small exceedance fractions, but only occasionally at larger exceedance fractions; basically predicting what was observed in practice.

\[f] According to the AIHA (Mulhausen and Damiano, 1998), a favorable initial assessment almost always should be verified with a follow-up survey within a reasonable time frame (e.g., less than a year).

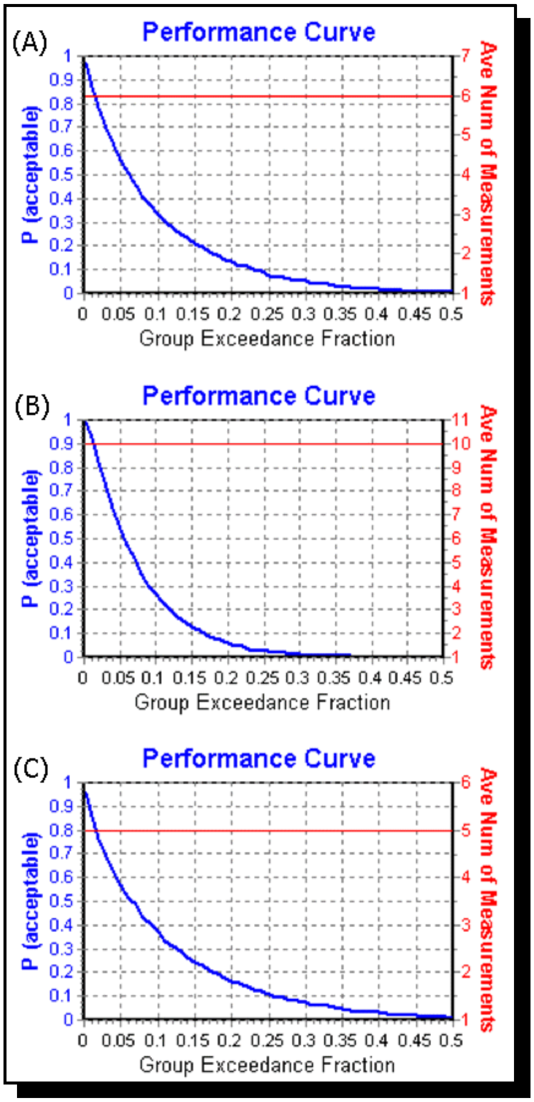

Figure 6: Predicted performance and sample size curves for the AIHA "SEG" strategy for three scenarios: (A) six workers are sampled, (B) ten workers are sampled, and (C) five workers are sampled.

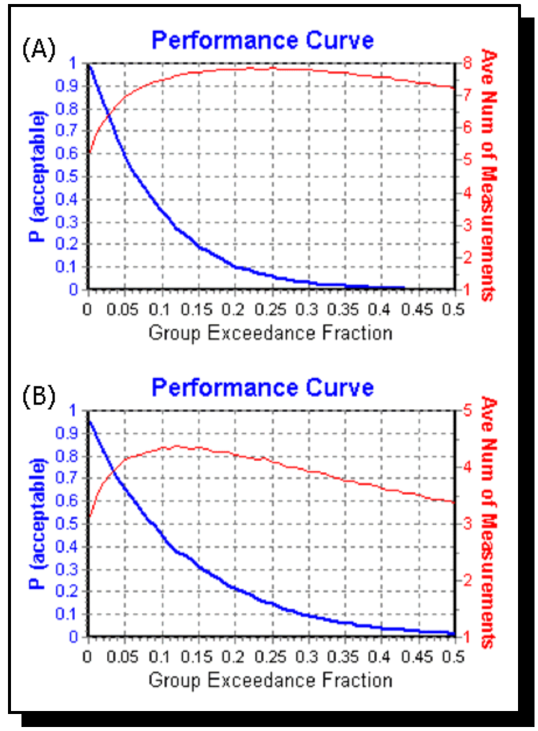

Figure 7: Predict performance and sample size curves for the Alcoa/Damiano strategy for (A) the default configuration and (B) the modified strategy (as discussed in the text).

Although Alcoa abandoned this strategy in the late 1990's (Damiano, 2001), the notion of a two-stage sampling scheme has considerable merit. Can the Alcoa strategy be tweaked to perform more efficiently without compromising its effectiveness? For example, the following modifications result in basically the same performance curve, but with a much improved efficiency curve (see Figure 7B): (1) reduce the baseline sample size to 3 and the maximum to 6, and (2) change the Rule B number greater than the OEL to 1, and (3) reduce the Rule B "percentage" threshold to 10%.

7.4.2 Comments

The Alcoa/Damiano strategy represents a clever approach to trying to minimize the overall sampling burden to the corporation, while at the same time retaining the ability to well characterize those work environments where exposures are neither clearly acceptable nor clearly unacceptable. Slight modification of the sample sizes for the first and second stages, coupled with tweaking of the decision rules, resulted in admirable performance and efficiency curves (Figure 7B).

7.5 CEN "HEG" Strategy

The CEN (1995) published a guideline on exposure assessment in which several example strategies were presented. The CEN recommended, for example, that when six or more measurements are collected the employer should analyze them statistically, estimate the group exceedance fraction, and compare the estimate to a critical value of 0.05. This approach is nearly identical to that presented by the AIHA in 1991 and 1998 (Hawkins et al., 1991; Mulhausen and Damiano, 1998). For situations where the employer must collect fewer measurements the CEN presented general guidance on interpreting limited datasets and presented example strategies in the appendices. In one example, the CEN suggested that employers consider adopting a two stage exposure sampling and data interpretation scheme (see Figure C.1 in CEN, 1995). We will call this scheme the CEN "HEG" strategy. A single measurement is collected from a "homogeneous exposure group". The group exposure profile is considered acceptable if this first measurement is less than 10% of the OEL. Otherwise, two additional measurements are collected. Exposures are acceptable if all three are less than 25% of the OEL, or all three are less than the limit and the geometric mean is less than 50% of the limit. If any single measurement exceeds the limit the employer should "take measures to reduce exposure" and then reevaluate.

According CEN monograph, this strategy does not lead to a specific decision whenever all three measurements are less than the limit but the geometric mean exceeds 50% of the limit. Presumably, at this point the industrial hygienist uses professional judgment to determine if additional measurements are necessary. In order to computer simulate this strategy we will assume that a geometric mean greater than 50% of the limit is unacceptable and triggers an additional exposure assessment of some sort.

7.5.1 Efficiency and Effectiveness

The performance curve for this strategy (as amended above) results in an unacceptable performance curve (see Figure 8A). The power to detect θ=0.25 is only 0.35. On the other hand, the efficiency curve (see Figure 8A) predicts that the average sample size will be less than approximately 2.5 measurements. If we change the strategy to where the 95th percentile is calculated and compared to 50% of the exposure limit (rather than the geometric mean) the performance curve (Figure 8B) improves to where the power to detect θ=0.25 is approximately 0.07. The efficiency curve does not change as we did not modify either the first or second stage sample sizes or any of the decision thresholds.

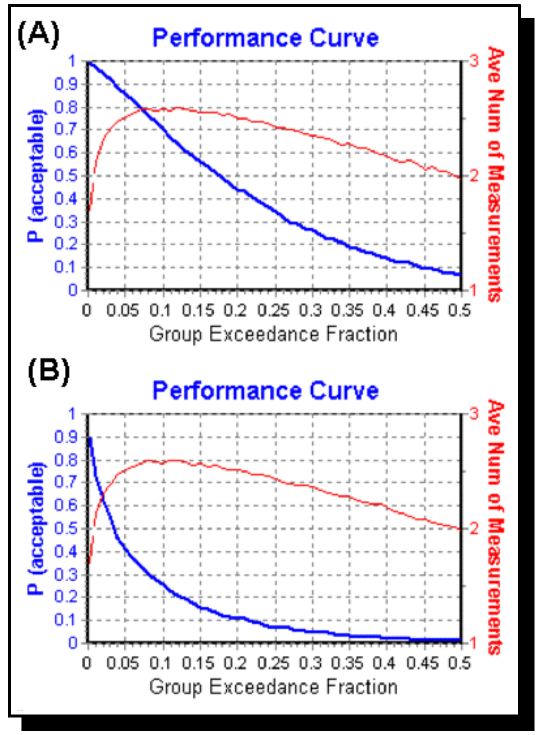

Figure 8: Performance and sample size curves for the CEN two-stage "HEG" strategy for (A) the default configuration and (B) the modified strategy (as discussed in the text).

7.5.2 Comments

The CEN (1995) presented several example strategies. I included this particular strategy because it represented a slightly different approach to a two-stage strategy. It combined both simple decision rules with a test of a distribution parameter. Its default configuration appeared to be premised on the common sense notion that if an employer collects very few measurements, in this case no more than n=3, then each of those measurements should be considerably less than the limit before one can reliably conclude that exposures are acceptable. Like the OSHA-NIOSH strategy, this is a remarkably flexible strategy, with many features that can be modified and fine tuned, to result in a wide range of performance curves.

8 DISCUSSION

I recommend that a logical process similar to that outlined earlier be used to evaluate and improve the performance of exposure assessment strategies, particularly when baseline exposure assessments are anticipated. The above examples demonstrate the use of this procedure and show that there is room for improvement in several commonly encountered strategies. Although computer simulation was used in each of the above example, the author does not suggest that every industrial hygienist become proficient at computer simulation. However, if a company or corporation rely upon an off–the-shelf or minimal legal strategy to detect poorly controlled work environments, then some attention should be given to evaluating the performance of that strategy. Below are additional considerations.

8.1 Minimizing Employees' Risk - Objective versus Goal

Even if computer simulation of the performance curve suggests that a specific exposure assessment strategy is likely to achieve the objective for baseline surveys, there is no guarantee that the goal of the exposure management program will likewise be achieved. This is because achieving the program goal - the control of exposures for all or most of the workers within an exposure group - depends on several factors:

- the heterogeneity of exposures within the exposure group in question
- decision errors resulting from any follow-up surveys required prior to implementing control strategies
- the effectiveness of new or improved control strategies
- the willingness of the employer to implement effective controls (engineering, work practices, or administrative) when suggested by the industrial hygienist or exposure control engineer.

Regarding the first factor, maintenance of the *group* exceedance fraction to 0.05 or less does not guarantee that the individual exposure profiles for the majority of workers are likewise acceptable.\[g] The second factor refers to the fact that an employer will undoubtedly *verify* the presence of an unacceptable exposure profile with one or more follow-up surveys before investing in any substantial improvements or modifications to existing controls.\[h] The sampling strategy used to collect and interpret these follow-up measurements will also have decision error probabilities.

8.2 Selection of the Corporate OEL

It is critical that a defensible OEL be selected. For example, a false sense of security is the likely result if an employer designs a sampling strategy to have a high power of detecting 25% overexposures relative to a PEL that originated with the 1968 TLVs, which in turn may have been based on risk assessments done decades earlier, when a more current TLV or other OEL is half as much or lower.

8.3 Within- and Between-Worker Exposure Variability

Much has been published over the past two decades regarding the need to evaluate within- and between-worker variability (Rappaport, 2000). In the above comparisons, it was assumed that the exposure group is moderately heterogeneous. Any computer simulation of strategy performance should include the ability to simulate real world within- and between-worker exposure variability. In addition, underlying any computer simulation is the assumption that the distributional models incorporated into the simulation are valid. The assumption here was that the lognormal distribution and a components-of-variance model are reasonable choices (see Hewett, 2005a).

8.4 Selection of Group Exposure Parameter

To reduce the complexity of this presentation, the group exceedance fraction was selected as the relevant group exposure parameter. However, the x-axis of the performance curve can be expressed in terms of other exposure parameters. For example, by setting the x-axis to "group 95th percentile" one can determine how far below the OEL the group 95th percentile must be, for a given strategy configuration, in order to reliably declare compliance (see Appendix D for an example). If the x-axis is set to 'exceedance fraction (worker 95th percentiles)' the user can evaluate whether or not meeting the strategy

\[g] Interested readers should review the discussion of "critical SEGs" in the AIHA monograph on exposure assessment (Mulhausen and Damiano, 1998) and in Hewett (2005a).

\[h] For this reason a large Employer's Risk can be tolerated for baseline (initial) exposure assessment surveys.

objective will also permit the exposure management goal to be achieved.\[i] (See Appendix B for more information on expressing the x-axis in terms other than group θ.)

8.5 Resource limitations

It will often be the case that users of this approach will find that additional resources will be needed to ensure a high power of detecting poorly controlled work environments, particularly if θ_2 is set lower than the 0.25 used here. The results of this type of simulation can be used to argue for additional resources. If sufficient additional resources cannot be obtained, then the alternative is to schedule re-assessments as soon as possible. The re-assessment is used to verify that an initial 'favorable assessment' was correct.\[j] Guidance on re-assessments can be found in Mulhausen and Damiano (1998). Regardless of the power of a particular strategy, routine surveillance is almost always necessary to detect any deterioration of work environment controls or changes in work practices. At a minimum, going through this exercise for a particular strategy will increase the employer's awareness of a strategy's strengths and weaknesses, hopefully leading to incremental improvements.

8.6 A Cautionary Note

In this report we used group exceedance fraction (θ) as the relevant exposure parameter *for instructional purposes*. Our definition of "clearly unacceptable" was θ=0.25, or one out of every four exposures is above the limit. Under the "clearly unacceptable" scenario the group 95th percentile exposure is more than 2.4 times the limit (assuming a geometric standard deviation of 2.5 and θ=0.25). Such a *lenient* definition of "clearly unacceptable" may be appropriate for low toxicity substances or for a beginning exposure assessment program. However, for a more mature exposure assessment program the corporate risk manager - e.g., the VP for EHS - is unlikely to be comfortable with this definition of "clearly acceptable", particularly for highly toxic substances.

When asked to define "clearly unacceptable" a corporate risk manager will often stipulate that the goal should be to be highly confident that the true 95th percentile exposure (or 99th if it is a highly toxic substance) is less than the limit (and not 2.4 times the limit as was used here). A strategy meeting this goal will of course be more stringent, particularly if exposures are not well controlled. But, if the corporation has controlled exposures for such highly toxic compounds to low levels, it is possible to design efficient strategies, using modified versions of the off-the-shelf strategies used in this report or custom strategies. An example of such a custom strategy is briefly presented in Section 8.12.

8.7 Believing the Measurements

A sampling strategy, no matter how effective the performance curve suggests it is likely to be, is of little use if the employer refuses to act when indicated by the strategy. For example, the performance curves of the OSHA Inspector and the OSHA-NIOSH 6b strategies are both based on presumption that the employer will investigate and take appropriate action if any single measurement exceeds the exposure limit. Say an employer has on paper adopted a modified version of the OSHA-NIOSH 6b strategy, yet in practice refuses to investigate and take appropriate action whenever any single measurement exceeds the OEL. In this case, the *theoretical performance curve* for the strategy, determined using the simulation module described here, will have little relation to the actual, or *field*, performance curve. In summary, the extent to which the computer simulations and the

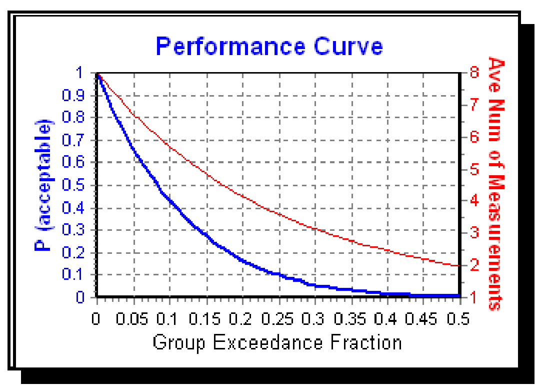

Figure 9: Predicted performance and sample size curve for the OSHA Inspector strategy for the scenario where a measurement is sequentially (e.g., one per month) collected from each of eight workers.

\[i] See EAS Inc. Technical Report 05-02 (Hewett, 2005b) for more information.

\[j] For example, say that for an existing strategy it was determined that the power at θ_2=0.25 is likely to be only 0.7. If a verification survey could be scheduled within say six months to a year, then the overall decision error would be (1-0.7)*(1-0.7) or 0.09, resulting in an overall power of 1-0.09, or 0.91.

resulting performance curves reflect actual, real world performance in large part depends upon the willingness of an employer *to react appropriately* when indicated by the strategy.

8.8 Investigating Each Overexposure

Regardless of the strategy, the investigation of each single overexposure is consistent with the guidance offered by several authoritative organizations. 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).

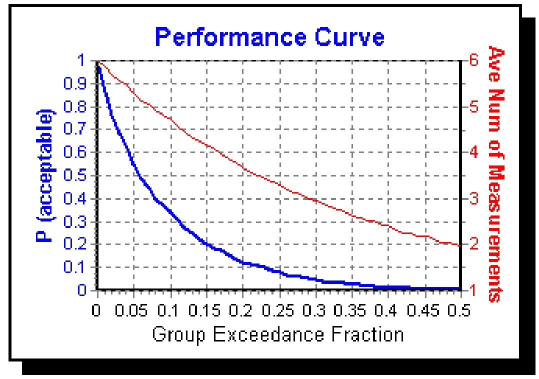

Figure 10: The default version of the AIHA strategy, but with sequential sampling.

8.9 Sequential Sampling vs. Campaign Sampling

In Section 7.2.2 we assumed that the measurements would be collected sequentially, which resulted in a much improved efficiency curve. Sequential, rather than campaign sampling, can be used for most other sampling strategies. The OSHA-NIOSH strategy is based upon sequential sampling. However, sequential sampling can be added to both the OSHA, AIHA and Alcoa/Damiano strategies. Sequential sampling would require that both strategies be supplemented with an additional rule: any measurement that exceeds X% of the exposure limit (in this case 100%) results in test failure and the conclusion that exposures are unacceptable. Figure 9 through 11 show the new performance and efficiency curves. Notice that the performance curves do not appreciably change. That is, this additional rule, which some might think is an onerous addition to the strategy, in fact does not lead to a different decision. The advantage lies in the efficiency curve, which in both cases is dramatically lower than the originals (in Figures 6A and 7B).

Another advantage to sequential sampling is that the measurements are spread out over time, providing a better picture of the overall exposure profile, and fewer measurements on average are required to reach a decision.

8.10 Censored Datasets

Simple, rule-based strategies, such as the OSHA-NIOSH 6b strategy and the OSHA inspector strategy, have often been criticized for not being statistically based. However, whenever a substantial fraction of measurements are less than the method limit-of-detection (LOD) the reliable estimation of exposure profile parameters becomes problematic. This is where a simple, rule-based strategy has the advantage.

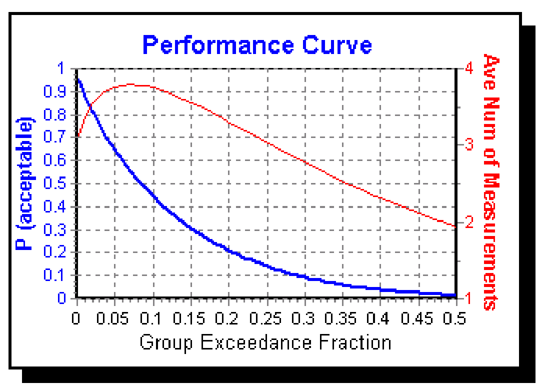

Figure 11: Alcoa/Damiano strategy (as modified in Section 7.4.1), but with sequential sampling.

For example, Figure 12 depicts the performance and efficiency curves for a simple two-stage, censored data strategy designed for a specific task. In this scenario the LOD is 10% of the exposure limit and experience has shown that the overwhelming majority of measurements are reported as LOD values. In this strategy, two measurements are collected. The exposures are declared acceptable is both measurements are less than the LOD. If either are above the LOD, but do not exceed 20% of the exposure limit, an additional three measurements are collected. If the additional three measurements are all less than 20% of the exposure limit, exposures are declared acceptable. Otherwise, exposures are unacceptable. Sequential sampling was used, with a cutoff at 20% of the exposure limit. In this scenario, the measurements are expected to be routinely less than 10% of the exposure. The second stage was added to accommodate the occasional measurement that will slightly exceed the LOD.

With this strategy the designers expected that measurements will routinely be less than the LOD, permitting an efficient and rapid decision at the first stage. If, however, the exposure profile shifted to the point that the true 95th percentile exposure equaled the exposure limit the probability of a false negative decision was limited to 0.05. Note that in this example the task 95th percentile exposure was used as the x-axis. To design this strategy the designers had to assume some maximum probable geometric standard deviation. Assuming that the true, but unknown geometric standard deviation remains similar to or less than the value chosen, this strategy will provide the corporation with at least 95% confidence that the true task-based 95th percentile exposure is less than the corporate limit.

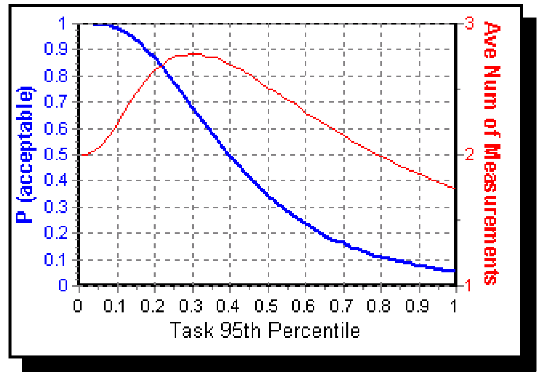

Figure 12: Performance and efficiency curve for a two-stage, censored data strategy. The x-axis is expressed as a fraction of the exposure limit.

In summary, a parameter-based strategy would be difficult to implement whenever the data are likely to be nearly 100% censored. A multi-stage non-parametric strategy (i.e., the data are compared to various actions levels to reach a decision; no statistics are calculated) may simply be the best solution for such situations.

8.11 Different Strategies for Different Toxicity Categories

It is possible to design a strategies for different classes of toxicity. For example, the AIHA suggests using four toxicity categories. A strategy designed for a high toxicity, category 4 exposure would probably be more stringent - i.e., have a lower probability of a false negative exposure assessment - than a strategy designed for a low toxicity, category 1 exposure.

8.12 Termination / Reduction Surveys

The emphasis in this paper has been on baseline or initial exposure assessment surveys. There are situations where an employer should assume that exposures are unacceptable and then seek compelling evidence that the exposure profile is controlled. For example, when

- reducing or terminating regular exposure monitoring
- switching from a mandatory respirator policy to a non-mandatory policy
- terminating medical surveillance for an exposure group
- removing employees from a hearing conservation program.

In these and similar instances the employer is basically testing the following hypotheses:

H_o: $\theta = \theta_1$ (unacceptable exposure profile)
H_a: $\theta < \theta_1$ (acceptable exposure profile)

The default hypothesis here is that the exposure profile is unacceptable, and only if compelling evidence is obtained will the alternative hypothesis be accepted. For termination/reduction surveys the employer should estimate the Employer's Risk at some clearly acceptable group exceedance fraction θ_2, where $\theta_2 < \theta_1$. Appendix D illustrates the application of performance-based strategy design when the goal is to reliably detect a clearly acceptable exposure profile.

9 CONCLUSIONS

Decision errors are unavoidable. Exposure assessment strategies that are implemented without consideration of their theoretical performance may result in the frequent failure to detect poorly-controlled work environments. Since a decision that an exposure profile is "acceptable" is likely to be extrapolated to all workers within a group and well into the future, it is important that the potential decision errors for baseline surveys be evaluated in advance of the surveys. Computer simulation can be used to predict the power of a strategy to detect poorly-controlled work environments. If the predicted power is less than the target level, then the strategy should be modified and the effect of the changes evaluated.

The primary goal of this paper was to introduce a methodology for designing performance-based strategies. Readers are encouraged to determine the power of their corporate strategy to detect poorly-controlled group exposure profiles. The author welcomes any suggestions for improvement or clarification.

10 ACKNOWLEDGMENTS

I would like to thank Mark Stenzel (Exposure Assessment Services, LLC) for recognizing the potential uses for performance-based strategy design and for recommending improvements to the computer simulation software.

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12 APPENDIX A - EXPOSURE GROUP CONCEPTUAL MODEL

VARIABLES

L - exposure limit
L_{TWA} - exposure limit for each worker's single-shift, time-weighted average exposure

x - a random, full-shift exposure for a randomly selected worker in a specific exposure group
G - geometric mean for the group exposure profile
G_P - geometric mean for the statistical distribution of 'worker 95th percentiles'
G_k - geometric mean for the exposure profile of the kth worker
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

X_q - the q·100%-tile of the group exposure profile; e.g., $X_{0.95}$ = 95th percentile of the group exposure profile.
P_q - the q·100%-tile of the statistical distribution of 'worker 95th percentile exposures'; e.g., $P_{0.95}$ = 95th percentile of distribution of 'worker 95th percentiles'.

P_k - 95th percentile exposure for the kth worker.
$\overline{M}$ - arithmetic mean for the group exposure profile; mean of the 'worker mean exposures'

Z - Z-value corresponding to a percentile of the group exposure profile
Z_P - Z-value corresponding to a percentile of the statistical distribution of 'worker 95th percentile exposures'

θ - theta; fraction of the group exposure profile that exceeds an exposure limit L; $P(x > L)$; probability that a random exposure for a randomly selected worker will exceed an exposure limit L
θ_P - fraction of the distribution of individual worker 95th percentiles that exceed the L_{TWA}; $P(P > L_{TWA})$

A popular model for conceptualizing group exposures, and the one recommended here, is based on the standard components-of-variance model for describing within- and between-factor effects. It has been applied to lognormally distributed exposure data in the instance where a true long-term average exposure limit applies[19] (Lyles, Kupper, and Rappaport, 1997; Rappaport, 2000). Here that model is expanded to encompass the far more common single shift, TWA exposure limits. See Hewett (2005b) for a more complete description.

This model 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 a 'group' geometric mean G, a "group" geometric standard deviation D, and a group heterogeneity coefficient ρ. The group geometric standard deviation D has two components: the between-worker and within-worker geometric standard deviations, or D_b and D_w, respectively. D_b refers to the geometric standard deviation for the statistical distribution of worker 'geometric means', while D_w refers to the within-worker geometric standard deviation for the distribution of day-to-day, full-shift, TWA exposures for a randomly selected worker. The relationship between D, D_w and D_b is as follows:

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

We will use ρ (rho), or the ratio of the between-worker variability to the group total variability, to indicate the level of group heterogeneity:

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

The variable ρ ranges between 0 and 1. Values of ρ near 0 indicate that the group is nearly homogeneous, meaning that the exposure profiles of individual workers do not differ greatly and are all similar to that of the entire group. Values of ρ approaching 1 indicate that the group is highly heterogeneous, meaning that the exposure profiles of individual workers are distinctly different from each other and all are considerably different from the overall group exposure profile. We can express D_b or D_w solely in terms of the group D and ρ:

$$\ln D_w = \sqrt{1-\rho} \cdot \ln D \qquad \text{Eq. 1}$$

$$\ln D_b = \sqrt{\rho} \cdot \ln D \qquad \text{Eq. 2}$$

The distributions of a variety of useful variables can be derived from the model. The overall group exposure profile can be described as the distribution of random exposures having a geometric mean G and a geometric standard deviation D :

$$\ln(x) \sim \mathbb{N}\left(\ln G , (\ln D)^2\right)$$

This relation is read as 'the log-transformed exposure (x) is normally distributed with a mean of lnG and a variance of $(\ln D)^2$.

The geometric mean of the *kth* worker is lognormally distributed:

$$\ln\left(G_k\right) \sim \mathbb{N}\left(\ln G , (\ln D_b)^2\right)$$

where G_k is the geometric mean for a randomly selected *kth* worker and D_b is the between-worker geometric standard deviation.

The log-transformed *jth* exposure for the *kth* worker is normally distributed:

$$\ln\left(x_{jk}\right) \sim \mathbb{N}\left(\ln G_k , (\ln D_w)^2\right)$$

where the geometric mean is unique to the *kth* worker. Notice that the model requires a common variance of $(\ln D_w)^2$ for all workers.

The log-transformed 95th percentile for the *kth* worker is also normally distributed:

$$\ln\left(P_k\right) \sim \mathbb{N}\left(\ln G + 1.645 \cdot \ln(D_w) , (\ln D_b)^2\right)$$

The true or population mean of the group exposure profile ($\bar{M}$) can be calculated from G and D using the following standard equation (Leidel, Busch, and Lynch, 1977):

$$\bar{M} = \exp\left(\ln G + \frac{1}{2}\cdot(\ln D)^2\right) = G \cdot \exp\left(\frac{1}{2}\cdot(\ln D)^2\right) \qquad \text{Eq. 3}$$

12.1 Calculation of Various Upper Percentiles

Any q·100%-tile of the group exposure profile can be calculated using the following equation:

$$X_q = \exp\left(\ln G + Z \cdot \ln D\right)$$

For example, if we are interested in the 95th percentile of the group exposure profile we replace Z with $Z_{0.95} = 1.645$:

$$X_{0.95} = \exp\left(\ln G + 1.645 \cdot \ln D\right) \qquad \text{Eq. 4}$$

Because each worker in the exposure group has a common within-worker geometric standard deviation, it follows that there will be a lognormal distribution for the 90th, 95th, 99th, or any other percentile worker exposure. The q·100%-tile of the distribution of "worker upper percentiles" can be calculated using the following equation:

$$P_q = \exp\left[\left(\ln G + K \cdot \ln D_w\right) + Z_P \cdot \ln D_b\right]$$

For example, if we are interested in the 95th percentile of the distribution of "worker 95th percentiles", we replace K with 1.645 and Z_P with 1.645. We can also substitute Equations 1 and 2 for $\ln D_w$ and $\ln D_b$ so that the final equation is in terms of G, D, and ρ:

$$P_{0.95} = \exp\left[\left(\ln G + 1.645 \cdot \sqrt{1-\rho} \cdot \ln D\right) + 1.645 \cdot \sqrt{\rho} \cdot \ln D\right] \qquad \text{Eq. 5}$$

Hereafter we will assume that $P_{0.95}$ refers to the 95th percentile "worker 95th percentile exposure".

12.2 Calculation of Exceedance Fractions

The fraction of group exposures exceeding any particular exposure limit L can determined from the following relation:

$$\theta = 1 - \Phi\left[\frac{\ln L - \ln G}{\ln D}\right]$$

The argument of the phi (Φ) function - 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.

The fraction (θ_P) of all group workers having a 95th percentile exposure greater than a L_{TWA} can be calculated:

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

Similarly, the fraction (θ_M) of all group workers having a mean exposure greater than a L_{LTA} can be calculated:

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

13 APPENDIX B - GENERATION OF RANDOM EXPOSURES

When testing the ability of a sampling strategy to detect poorly-controlled group exposure profiles it is necessary to generate random exposures (Hewett, 1999 AIHCE; Hewett, 2002 AIHCE) (Hewett, 1999, 2005a, 2005b). The artificial data are then analyzed and interpreted according to the specified strategy. Such artificial exposure assessment surveys are then repeated hundreds to thousands of times. Counter variables are used to keep track of the number of artificial surveys that lead to a decision that the exposure profile was acceptable. The COV model presented here can be used to generate random exposure measurements for exposure groups having specific amounts of within- and between-worker variability.

13.1 Procedure when G, D, and ρ are specified

For a fixed geometric standard deviation (D) and level of group heterogeneity (discussed in Appendix A), the corresponding group geometric mean (G) can be calculated (see Appendix B) as well as the within- and between-worker geometric standard deviations (using a components-of-variance model for log-transformed exposures). The group geometric mean and the between-worker D are then used to computer generate a geometric mean for the exposure profile of a randomly selected worker. This worker-specific G is paired with the within-worker D to generate a random exposure. This process is repeated for as many workers (or measurements per worker) as are necessary for each survey.

For simulating sampling strategies where maximum risk employees are selected, one or more employees may be sampled more than once, or the strategy requires the estimation of the within- and between-worker variance components, the following general steps can be used to simulate exposure measurements:

1. Specify G, D, and ρ for a hypothetical exposure group.

2. Using D and ρ , calculate D_w and D_b using Equations 1 and 2, presented earlier.

3. Generate a geometric mean (G_k) for a randomly selected worker:

$$random\ G_k = \exp\left(\ln G + Z \cdot \ln D_b\right)$$

where Z is randomly generated from a standardized normal distribution: Z ~ ℕ(0,1). Functions that generate random Z-values can be found in most programming languages, statistical packages, mathematics programs, or spreadsheets. Note that each randomly generated Z-value should be used only once.\[k]

4. Generate a random exposure for this random worker:

$$x_{jk} = \exp\left(lnG_k + Z \cdot \ln D_w\right)$$

where Z is randomly generated from a distribution that is ℕ(0,1).

13.2 Procedure when only G and D are specified

There are strategies that do not require or permit repeat sampling of each worker. The AIHA strategy (Mulhausen and Damiano, 1998) (see also Hewett, 2005a) specifies that for initial surveys a single measurement should be collected from each of *n* randomly selected workers. For this and similar strategies where between-worker variability is not a factor the following general steps can be used to simulate exposure measurements:

1. Specify G and D.

\[k] If such a function is not available, a random value from an approximate ℕ(0,1) distribution can be generated by summing twelve random values from the uniform distribution, and then subtracting six. For example, using a spreadsheet one can use the “rand” function to generate a single random uniform variate. Therefore, a random z would equal "rand+rand+...+rand - 6", where there are twelve rand functions in the equation. This is not best method for generating random z-values, but it works well enough for all but the most discriminating user. A superior method for generating random Z-values is the Marsaglia-Bray algorithm .

2. Generate a random exposure:

$$x_j = \exp\left(lnG + Z \cdot \ln D\right)$$

where Z is randomly generated from a distribution that is ℕ(0,1).

13.3 Calculation of the Group Geometric Mean

In both 13.1 and 13.2 a group geometric mean G is necessary for generating random exposures. However, we often do not start with G, but with some other value derived from the group exposure profile. For example, we may be interested in determining the ability of a strategy to detect some clearly unacceptable group exceedance fraction θ; e.g., θ = 0.25 (Hewett, 2005a). Consequently, we need to determine the group geometric mean (given that D has already been specified) corresponding to θ=0.25. The following equations are useful for determining the group geometric mean G that corresponds to θ, as well as other parameters of interest.

Given θ, the group exceedance fraction, calculate G :\[1]

$$Z_x = \Phi^{-1}\left[1-\theta\right] \qquad \text{Eq. 3}$$

$$G = \exp\left(\ln L - Z_x \cdot \ln D\right) \qquad \text{Eq. 4}$$

Given θ_P, the exceedance fraction for worker 95th percentiles, calculate G :

$$Z_P = \Phi^{-1}\left[1-\theta_P\right]$$

$$G_P = \exp\left(\ln L_{TWA} - Z_P \cdot \ln D_b\right)$$

$$G = \exp\left(\ln G_P - 1.645 \cdot \ln D_w\right)$$

Given $X_{0.95}$, the group 95th percentile exposure, calculate G :

$$G = \exp\left(\ln X_{0.95} - 1.645 \cdot \ln D\right) = \frac{X_{0.95}}{D^{1.645}}$$

Given $\bar{M}$, the group mean exposure, calculate G :

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

\[1] The function Φ^{-1} refers to the inverse of the Z-distribution, i.e., the Z-value corresponding to 1-θ.

14 APPENDIX C - OUTLINE OF SELECTED STRATEGIES

Abbreviations: OEL = occupational exposure limit; C = concentration; AL= action level

14.1 OSHA-NIOSH Strategy published by Leidel, Busch, and Lynch (1977):

Data Collection
- Select an exposure group.
- Identify 1 or more 'representative employees'.[m]
- Collect 1 measurement from each employee.

Data Analysis
- No statistical analysis is required. Each measurement is directly compared to the OEL and Action Limit (AL; usually 50% of the OEL)

Data Interpretation
- If the initial C < AL, then work environment appears acceptable. Monitoring may be reduced or eliminated.
- If any C > OEL, then investigate and take appropriate action.
- If AL ≤ initial C ≤ OEL, then collect additional measurements until two consecutive measurements are <AL, or any C > OEL.
- If two consecutive measurements are <AL, then monitoring may be reduced or eliminated.

14.2 OSHA Inspector strategy (OSHA, 2003b), as interpreted by the author:

Data Collection
- Select an exposure group.
- Identify 1 or more employees.
- Collect 1 measurement from each.

Data Analysis
- No statistical analysis is required. Each measurement (C) is directly compared to the OEL.

Data Interpretation
- If each C ≤ OEL, then the exposure profile appears acceptable.
- If any C > OEL, then investigate and take appropriate action.

14.3 AIHA Similar Exposure Group (SEG) Strategy (Mulhausen and Damiano, 1998):

Data Collection
- Select a "similar exposure group".
- Randomly select 6 or more workers (6 to 10 is recommended)
- Collect 1 measurement from each worker.

Data Analysis
- Estimate the group upper percentile (e.g., 95^{th} percentile) and its UCL.

Data Interpretation
- If the upper percentile is ≤ OEL, then work environment appears acceptable, reassess to confirm.
- If the upper percentile is > OEL, then investigate and take appropriate action.
- If the UCL ≤ OEL, then work environment is acceptable (with at least X% confidence).

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[m] OSHA has consistently defined 'representative employee' as an employee known or suspected to routinely experience higher exposures.

14.4 Alcoa/Damiano Strategy (Damiano, 1995):

Data Collection **-** *Stage 1*

- Select a "homogeneous exposure group".
- Randomly select 5 workers and collect 1 measurement from each worker.
- (A) Are all 5 measurements < 50% of the OEL?
  (B) Are 2 or more measurements > OEL and the remaining $\geq$ 50% of the OEL?
  If the answer is yes to either question, then proceed to *Data Analysis*, otherwise go to Stage 2 data collection.

Data Collection **-** *Stage 2*

- Randomly select 3 workers and collect 1 measurement from each worker.

Data Analysis

- Combine Stage 1 and Stage 2 (if any) measurements.
- Estimate the group 95th percentile.

Data Interpretation

- If the 95th percentile is $\leq$ OEL, then the work environment appears acceptable.
- If the 95th percentile is > OEL, then investigate and take appropriate action.

14.5 CEN Example Strategy (CEN, 1995), as interpreted by the author:

Data Collection **-** *Stage 1*

- Select a "homogeneous exposure group".
- Randomly select 1 worker and collect 1 measurement
  Is the measurement < 10% of the OEL?
  If yes, then proceed to *Data Interpretation*. If not, go to Stage 2 data collection.

Data Collection **-** *Stage 2*

- Randomly select 2 additional workers and collect 1 measurement from each worker.
  Are all three measurements < 25% of the OEL?
  If yes, proceed to *Data Interpretation*. If not, proceed to *Data Analysis*.

Data Analysis

- Combine Stage 1 and Stage 2 measurements.
- Estimate the group geometric mean.

Data Interpretation

- The work environment appears acceptable if the first measurement is < 10% of the OEL.
- Otherwise, the work environment appears acceptable if one of the following conditions apply:
  - All measurements are < 25% of the OEL, or
  - the geometric mean is < 50% of the OEL.
- Otherwise, implement "measures to reduce exposure" and start again.*
- If any measurement exceeds the OEL, then implement "measures to reduce exposure" and start again.

* The published version of this strategy does not lead to a specific decision whenever all three measurements are less than the limit but the geometric mean exceeds 50% of the limit. Presumably, at this point the industrial hygienist uses professional judgment to determine if additional measurements are necessary. In order to computer simulate this strategy we will assume that a geometric mean greater than 50% of the limit is unacceptable and triggers an additional exposure assessment of some form.

15 APPENDIX D - DESIGN OF A PERFORMANCE-BASED TERMINATION-REDUCTION STRATEGY

The U.S. Department of Energy (DOE, 1999) stated that DOE contractors will "adequately characterize exposures before reducing or terminating monitoring". Here the DOE expects contractors to be highly confident that exposures are controlled before reducing or terminating regular exposure monitoring. There are also other scenarios where an employer should be highly confident that exposures are appropriately controlled before taking action, such as when removing workers from medical surveillance, a mandatory respiratory PPE program, or a hearing conservation program. For such scenarios the employer is basically implementing a termination-reduction exposure assessment strategy where the hypotheses to be tested are:

H_o: $\theta = \theta_1$ (unacceptable exposure profile)
H_a: $\theta < \theta_1$ (acceptable exposure profile)

Here the alternative hypothesis - H_a - is the reverse of that tested with a baseline survey. Before we concentrated on reliably detecting a *clearly unacceptable* exposure profile. Here we are interested in reliably detecting a *clearly acceptable* exposure profile. In order to design a performance-based strategy for testing these hypotheses we ask the question "What is a clearly acceptable exposure profile?" Earlier I suggested that a clearly acceptable exposure profile might be one where the true exceedance fraction is 0.01. The question now is "If the true exceedance fraction is 0.01, will the proposed strategy allow us to reject the null hypothesis and accept the alternative hypothesis 90% of the time?"

To demonstrate the use of other exposure parameters we will recast the above hypotheses to be terms of the group 95th percentile exposure. Consider the following scenario:

> Exposures for an SEG occasionally exceeded an OSHA PEL and frequently were between the Action Limit and PEL. Consequently, the employer was obligated to develop and maintain exposure monitoring and medical surveillance programs, as well as a PPE program for specific tasks. Over a period of several years the employer reduced exposures through improved work practices, modifications to existing local exhaust systems, and partial containment of specific tasks found to contribute greatly to both individual and general exposure levels.
>
> Recent exposure measurements suggest that the group 95th percentile exposure is now less than 10% of the PEL (and that the group geometric standard deviation is around 2.5).\[n] The employer would like to eliminate regular exposure monitoring and the medical surveillance program. The employer and the IH staff decided to use the upper tolerance limit approach advocated by the AIHA for decision making whenever high confidence is needed (Mulhausen and Damiano, 1998).

The hypotheses to be tested are:

H_o: $X_{0.95} = ½·OEL$ (unacceptable exposure profile)
H_a: $X_{0.95} < ½·OEL$ (acceptable exposure profile)

\[n] Increasing the level of control from general dilution to local exhaust, or moving from some form of local exhaust to containment, can reduce exposures by an order of magnitude. (Maidment, 1998).

A set of n measurements will be collected: a single measurement from each of n randomly selected employees. The 90%UCL for the 95th percentile will be calculated and compared to the Action Limit (i.e., ½·OEL). The alternative hypothesis H_a will be accepted if and only if the 90%UCL($X_{0.95}$) is less than the Action Limit. At this point the employer will conclude, with at least 90% confidence, that the true group 95th percentile is less than the Action Limit.

How many measurements will be required to reach this conclusion 90% of the time whenever the true 95th percentile exposure is at (or below) 10% of the OEL? Using the procedures discussed earlier, we first did a computer simulation using n=6 measurements. The performance curve for this strategy is shown in Figure 12A. With n=6 measurements the power to detect $X_{0.95}$=0.10·OEL is slightly less than 0.70, which does not meet the target power of 0.90. Figure 9B shows the power will be approximately 0.90 if the sample size is increased to n=10.\º

The employer now has an idea of the type of strategy, data analysis scheme, and sample size necessary to test the hypothesis that the true group 95th percentile exposure is less than the Action Limit.

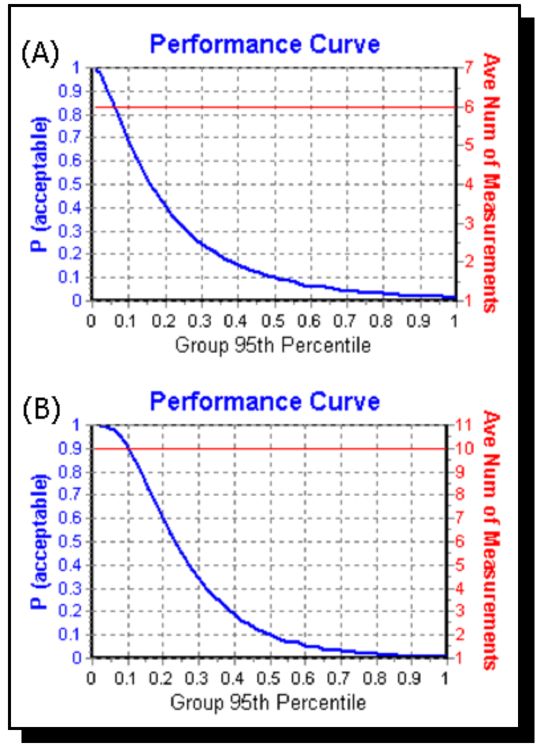

Figure 13: Termination/reduction strategy performance and sample size curves for two scenarios: (A) six workers are sampled, and (B) ten workers are sampled. The x-axis is expressed as the group 95th percentile as a fraction of the PEL.

\º Note that because we used the 90%UCL for the 95th percentile the performance curve is *fixed* at 0.10 where $X_{0.95}$=0.5·PEL. Changes in the sample size will not affect this point on the performance curve, but will affect the y-axis location of the performance curve where $X_{0.95}$=0.1·PEL.