

TECHNICAL APPENDIX J

CONFIDENCE LIMITS AND CONFIDENCE LEVELS AS THEY AFFECT EMPLOYEE AND EMPLOYER RISK

In section 1.5 it was stated that because of the effect of random measurement errors, any exposure average for an employee calculated from exposure measurements is only an estimate of the unknown true exposure average. The procedures of Chapter 4 take into account the random differences between the measured exposure average and the true exposure average. Decision statements can be made regarding the value of the true exposure average relative to an occupational health standard. These decision statements have a predetermined risk level or confidence level associated with them. This Appendix will discuss the effect of choosing different risk levels on the probabilities of declaring compliance or noncompliance. The concepts of confidence interval limits, hypothesis testing, type I and II errors, and power function curves will first be discussed to build a background for comparing risk levels.

CONFIDENCE INTERVAL LIMITS

The procedures of Chapter 4, particularly sections 4.2.1 and 4.2.2, are statistical hypothesis testing in the framework of confidence limits. Section 4.1 discussed the relation of the one-sided lower confidence limit (LCL) and one-sided upper confidence limit (UCL) to decision statements of compliance exposure, possible overexposure, and noncompliance exposure. It is useful to elaborate here on the purpose and utility of confidence interval limits when making decisions regarding the true exposure average.

Suppose an employee had a true exposure average of 80 ppm on a particular day. A sampling and analytical procedure having a total coefficient of variation (CV_T) of 10% was used to measure the 8-hour TWA exposure with one

8-hour full period sample measurement. If it were possible to obtain many simultaneous 8-hour samples on the same day for the same employee, the sample results would be distributed as shown in Figure J-1. Of course, one would usually only take a single measurement on a day to estimate the employee's exposure average. We would like to make a quantitative statement concerning the value of the unknown true average based on our one actual measurement.

The sampling distribution of Figure J-1 shows the relative frequency of the many possible values we might find with our one measurement. Several points are worth noting. About 68% of the possible sample values lie within the region centered about the true average exposure, from 72 ppm ($\mu - \sigma$) to 88 ppm ($\mu + \sigma$). Thus, there is a 68% probability that our one sample will fall within $\pm 10\%$ (± 8 ppm or $\pm \sigma$) of the true average exposure. But, about one-third of the time it could fall, by chance, outside this narrow central region. A larger region from 64.3 ppm ($\mu - 1.96\sigma$) to 95.7 ppm ($\mu + 1.96\sigma$) contains 95% of all possible measurement values. As noted in Appendix D, this sampling and analytical method would be said to have a 95% confidence level accuracy of about 20% ($1.96 \times CV_T$) since single 8-hour measurements would lie within $\pm 20\%$ of the true average exposure 95% of the time.

The true exposure is always unknown. But we do know the sampling/analytical method's CV_T , the sample size (one, in this example), and we assume normally distributed errors (as shown in Figure J-1). From this information, we can calculate confidence limits, which bound a two-sided interval around the measured exposure, that will probably contain the true mean. The high probability that the computed interval

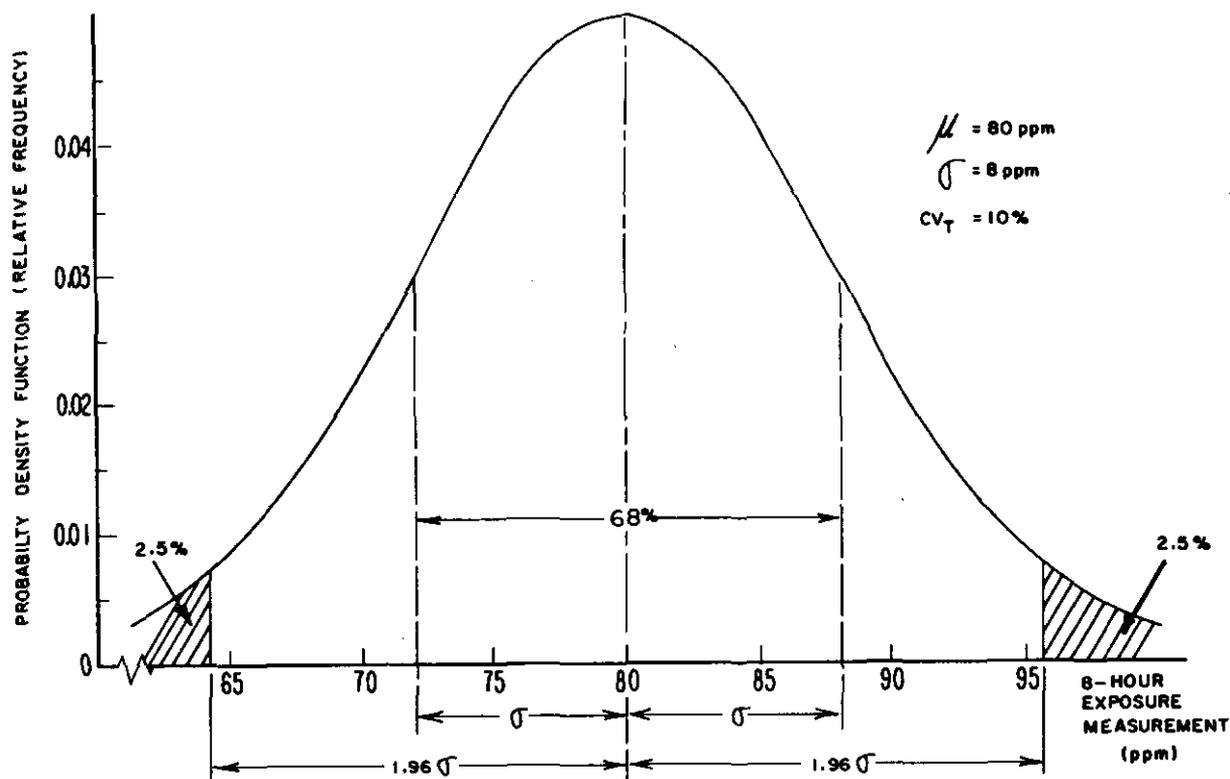


Figure J-1. Predicted sampling distribution of simultaneous single 8-hour samples from an employee with a true exposure average (μ) of 80 ppm. Samples obtained with a $CV_T=0.10$ sampling/analytical method (about $\pm 20\%$ accuracy at 95% confidence level).

will contain the true exposure average is called the confidence level. Natrella (J-1) has several illustrations (Natrella's Figures 1-8 through 1-10) demonstrating this point. Generally, we choose the 95% confidence level (i.e., confidence coefficient of 0.95) in computing the limits. The word *probability*, as used here in connection with confidence level, refers to the relative frequency (i.e., proportion of cases) of confidence limits that would, in fact, contain the true value as stated. Thus, in the long run 95% of the confidence intervals computed by the appropriate statistical procedure at a confidence level of 95% would be expected to contain the respective true exposure averages. Therefore, since we only take one measurement of a given employee's exposure, there is a 5% risk (i.e., probability) that the calculated two-sided 95% confidence limits do not include the true average on that occasion.

Sometimes we are only interested in an upper bound that has a high probability of exceeding the true average or in a lower bound that has

a high probability of being below the true average. As an example of the use of an upper bound, we might want to ensure that the true average is less than a threshold limit value (TLV) or Occupational Safety and Health Administration (OSHA) standard, apart from a 1 in 20 chance. To pass the test, the 95% one-sided UCL must be less than the standard. This concept is elaborated on in section 4.1.

To summarize the concept of confidence limits, we see that we don't have to be content with only reporting that the true exposure average has a value somewhere near the measured average. We make use of the sampling distribution (based on the known accuracy of the sampling/analytical method) to construct either a two-sided confidence interval around the measured average or a one-sided confidence interval (i.e., upper bound or lower bound) on one side of the measured average. Then we can state (at a desired confidence level) that the two-sided interval (or either one-sided interval) contains the true average. The chance that we

might be unlucky enough to get a measurement so far from the true mean that the confidence interval does not contain the true average is the risk level of the confidence interval statement. The term *risk level* is used here to mean the complement of the confidence level; e.g., a 95% confidence interval would have a 5% risk level (100% - 95% = 5% probability of *not* including the true average exposure).

TESTS OF SIGNIFICANCE OR HYPOTHESIS TESTING

The decision tests of Chapter 4 based on confidence intervals are algebraically equivalent to appropriate statistical tests of significance. It is useful to discuss the concepts and terminology of significance and hypothesis testing and compare them with decisions based on confidence intervals.

The industrial hygienist is interested in testing a hypothesis concerning the value of the true exposure average relative to a TLV or standard. In this context, a hypothesis is an assumption about the state of the true exposure average μ . Statistical significance tests involve two hypotheses. Before the exposure measurement is made, a tentative assumption about the value of the total exposure average relative to the standard is made. This tentative assumption is then accepted unless it is *proven wrong* by the statistical test. By *proven wrong*, we mean that the sampling measurements actually obtained would have had low probability (e.g., less than 0.05) of occurring before the samples were taken if the tentative assumption were true. This tentative negative hypothesis is called the *null hypothesis*. Correspondingly, an alternative assumption, referred to as the *alternative hypothesis*, is made. This alternative hypothesis must be accepted whenever the null hypothesis is rejected. These hypotheses are based on the philosophy of the industrial hygienist. The philosophies of an employer and a governmental compliance officer would differ and the appropriate points of view are discussed below.

HYPOTHESES FOR THE EMPLOYER

Each employer is required to furnish to each of his employees a place of employment free from recognized hazards that are likely to cause death or serious injury. To do this, the employer must keep true employee exposures

at levels below the appropriate TLV's or standards. Thus, the employer must make decisions regarding his exposure measurements in such a manner that he is confident that there is no employee whose average exposure exceeds the average exposure standards and that no employee will at any time be exposed to levels above the ceiling exposure standards. In statistical terms, the employer must formulate the null hypothesis that the true exposure exceeds the standard and put the "burden of proof" on the data, which must indicate compliance after allowing for random measurement variability. For the Employer's Test for Compliance:

Null hypothesis is $H_0: \mu > \text{standard}$, i.e., noncompliance

Alternative hypothesis is $H_A: \mu \leq \text{standard}$, i.e., compliance

HYPOTHESES FOR COMPLIANCE OFFICER

The governmental agency has to meet the substantial evidence test and has the burden of proving that a health standard has been exceeded on a particular day. This is because the OSHA health standards are either average exposure standards defined for an 8-hour averaging period or ceiling exposure standards that at no time shall be exceeded (29 CFR 1910.1000). Therefore, the compliance officer should state the null and alternative hypotheses such that the data must indicate noncompliance after allowing for random measurement variability. For the Compliance Officer's Test for Noncompliance:

Null hypothesis is $H_0: \mu \leq \text{standard}$, i.e., compliance

Alternative hypothesis $H_A: \mu > \text{standard}$, i.e., noncompliance

ERRORS IN HYPOTHESIS TESTING

When we used the confidence interval as test criterion for the measured exposure average (\bar{X}^*), we realized there was a risk that the confidence interval did not include the true exposure average. Hypothesis testing uses the terms *type I* and *type II errors* to describe the two types of wrong decisions we might make based on the results of our tests. If we reject the null hypothesis (accept the alternative hypothesis) when the null hypothesis is really true, we commit a type I error. On the other hand, if we fail to reject the null hypothesis

when it is truly false, then we commit a type II error.

In the context of the compliance officer's and employer's tests:

COMPLIANCE OFFICER'S TEST FOR NONCOMPLIANCE

Test result	True state	
	Compliance with standard	Noncompliance with standard
Decide compliance	No Error	Type II error
Decide noncompliance	Type I error	No Error

EMPLOYER'S TEST FOR COMPLIANCE

Test result	True state	
	Compliance with standard	Noncompliance with standard
Decide compliance	No Error	Type I error
Decide noncompliance	Type II error	No Error

To clarify the interpretation of the statistical decision procedure, we will discuss the decision table used by compliance officers. In Chapter 4, we formulated a decision criterion for use by compliance officers:

- Reject H_0 : $\mu \leq$ standard and
- Accept H_A : $\mu >$ standard whenever a confidence interval for the true mean at the $100(1-\alpha)\%$ confidence level does not contain the standard.

The risk (probability) of making a *type I error* is designated α . The *maximum* value of α is the test's level of significance. Note that the confidence level $(1-\alpha)$ is the complement of the probability α of a type I error. This is true because our decision rule is based on a confidence interval but was formulated to be algebraically equivalent to an α -level significance test of the null hypothesis H_0 . Thus, a decision rule based on a 95% confidence interval is the same as a significance test with a 5% maximum risk of committing a type I error.

The risk of making a type II error is designated by β . The value of β varies with magnitude of the real difference between the standard and the true exposure average. The relation between these two types of risks can be sum-

marized on either an operating characteristic (OC) curve for the test or the power function (PF) curve discussed below. The *power* of the test is the probability of accepting the alternative hypothesis when the alternative hypothesis is true. The *power* is designated by $(1-\beta)$, the complement of the probability of a type II error.

RELATION OF CONFIDENCE LIMITS TO TESTS OF SIGNIFICANCE

The equivalence of the Chapter 4 tests to appropriate tests of significance has been indicated above and will not be demonstrated in this Technical Appendix. Suffice it to say, our decision rules are equivalent to significance tests of the null hypotheses given above. Chapter 21 of Natrella (J-1) has an excellent discussion comparing the two approaches. We prefer the LCL and UCL approach since the magnitude of the difference between the LCL (or UCL) and the standard gives an idea of how firm our decision is. Other texts such as Bowker and Lieberman (J-2), Crow et al. (J-3), and Snedecor and Cochran (J-4) can be consulted for further information on these topics.

POWER FUNCTION CURVES

Earlier the term *95% confidence level* was introduced in reference to statistical hypothesis testing. The term arose from the choice of a *5% risk level* for the equivalent statistical significance test to be used. The clear advantage of using statistical tests for the decision process regarding exposure standards is that the maximum desired risk levels can be selected in advance and power function probability curves can be calculated. The PF curve gives the power $(1-\beta)$ of the test as a function of the true mean μ . Bartlett and Provost (J-5) have shown how standards, tolerances, and risk levels can be interpreted in up to five different ways. Employers, government inspectors, and employees can all interpret a standard in different ways. The interpretations involve sample size, chosen confidence (risk) levels, and acceptance/rejection criteria.

A way of illustrating the various interpretations is through the PF curves for each test. The PF is the complement of the OC function. Operating characteristic curves for many of the conventional statistical tests are given in Natrella (J-1) and Bowker and Lieberman (J-2). We will calculate similar power func-

tions for the tests of sections 4.2.1 and 4.2.2. In these tests, the CV_T is assumed to be known without error when testing the null hypothesis that the true mean equals the OSHA standard. Therefore, the quantity $1.645 CV_T \sqrt{n}$ constitutes an allowance for sampling and analytical error in the sample mean of standardized concentrations. More specifically, in this formula, the factor 1.645 is the 95th percentile of the standardized normal distribution. The error allowance given by the above formula is added to the sample mean to compute a one-tailed upper (or subtracted from the sample mean to compute a one-tailed lower) 95% confidence limit for the true mean standardized concentration, according to sections 4.2.1 and 4.2.2. (For a discussion of the sense in which the term *confidence limit* is used, see "Statistical Note" in section 4.2.1.) A more exact 95% limit of error could be calculated by taking into account, that there is an error of estimate in CV_T as well as \bar{x} . (The CV_T values given in Technical Appendix D for the NIOSH sampling/analytical methods were obtained from six samples at each of three contaminant concentrations.) If this were done, it would be necessary for most methods to increase the multiplier 1.645 by about 10% to account for the uncertainty in the experimental estimate of CV_T . However, the exact multipliers to replace 1.645 cannot yet be calculated because our CV_T values were estimated from samples collected using a carefully controlled flow rate through a critical orifice. The CV for additional field error accountable to the personal sampling pump (denoted by CV_P) had to be "added in" using a conservative to obtain the CV_T values of Technical Appendix D.

We have treated the CV_T as a known quantity* and used the normal distribution (not the Student-t) as a basis for the test statistic and for the corresponding power functions given further below. We believe that when the corrections are made, using an experimental estimate of CV_P in place of 0.05, the net effect of the refinements will be negligible because the two corrections are expected to be in opposite directions. The factor 1.645 will increase

*When a good experimental CV_P estimate becomes available, NIOSH will publish a new table giving revised CV_T estimates, along with refined (i.e., slightly increased) multipliers to replace 1.645.

slightly, but the CV_P estimate (a component of CV_T) is expected to be lower than 0.05. To summarize, we believe that the test statistics given in sections 4.2.1 and 4.2.2, as well as the power function curves given in this section, are sufficiently accurate. However, to be conservative (until a good experimental estimate of pump error becomes available), half-widths of confidence intervals could be increased by about 10% (i.e., use 1.81 in place of 1.645).

The following discussion concerns calculating the power curves. Figure J-2 is for the Employer's Test to ensure compliance; the test statistic (section 4.2.2.1) is

$$UCL (95\%) = \bar{x} + \frac{1.645 (CV_T)}{\sqrt{n}}$$

where 1.645 is the 95% point (one-sided) of the normal distribution.

The test rejects the null hypothesis H_0 of noncompliance and chooses the alternative hypothesis H_A of compliance exposure if $UCL < 1$. An equivalent decision rule is

$$[\bar{x}] < \left[1 - \frac{1.645 (CV_T)}{\sqrt{n}} \right]$$

for compliance exposure.

Example:

For one 8-hour full period sample ($n=1$) and for $CV_T=0.10$,

$$[\bar{x}] < 0.8355$$

for compliance exposure.

For the PF curve, we must consider all the possible standardized sample values (\bar{x}) that could arise and which of them would lead to rejection of the null hypothesis. Suppose the true standardized exposure average μ/STD was 0.9, i.e., the employer is in compliance by a margin of 10%. When he tests the null hypothesis of noncompliance, the power of the test is the probability that the test data will yield a decision of compliance, i.e., reject the null hypothesis. The probability of rejecting H_0 is:

$$\text{Prob } [\bar{x} < 0.8355]$$

We compute the standard normal variable:

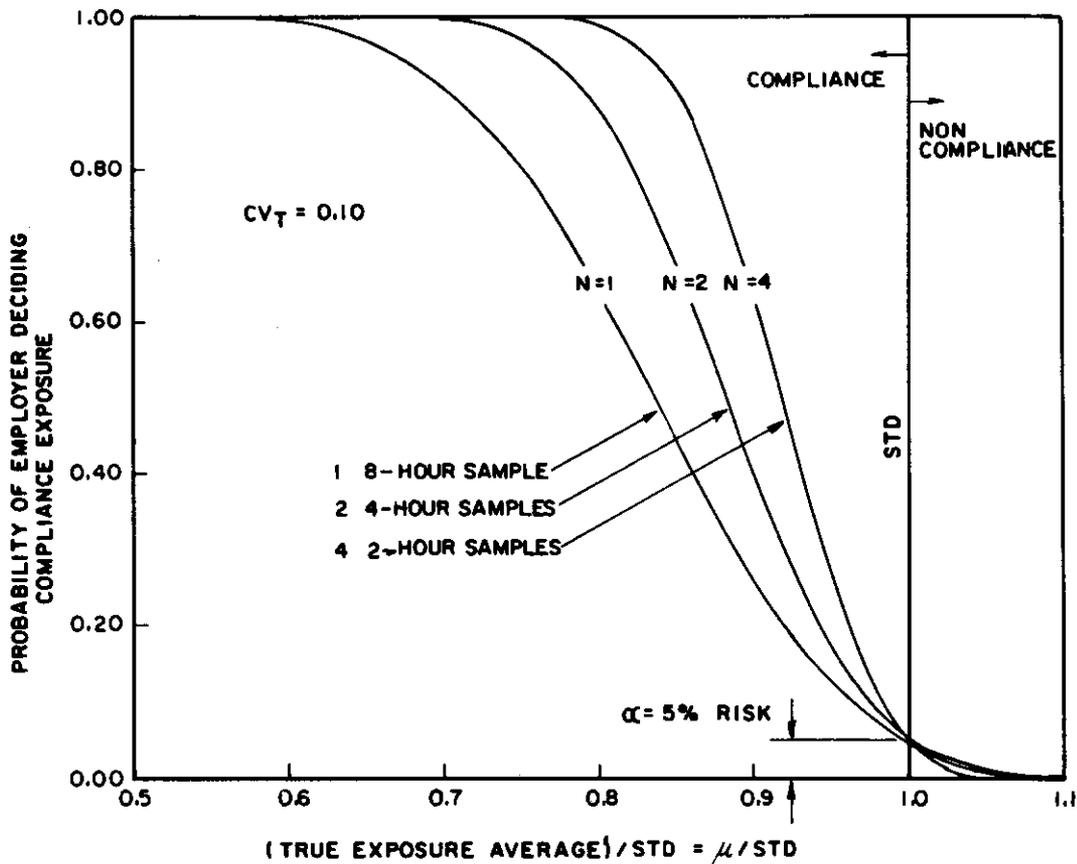


Figure J-2. Power function (PF) curve for one-sided Employer's Test (5% risk level) to ensure compliance as given in sections 4.2.1 and 4.2.2. Calculated for sampling/analytical method with $CV_T = 0.10$ (about $\pm 20\%$ accuracy at 95% confidence level).

$$z = \frac{(0.8355 - 0.9)}{CV_T / \sqrt{n}} = \frac{-0.0645}{0.10 / \sqrt{1}} = -0.645$$

The probability of rejecting H_0 is the probability of obtaining a value less than (-0.645) from a standard normal distribution (mean 0, variance 1).

$$\text{Prob} [z < (-0.645)] \approx 0.26$$

In this way, the standard normal distribution was used to compute the curves of Figures J-2 through J-6. The calculations were performed on a Wang 2200 calculator using program PS.01-2200.01A-00F1-16-0 to compute integrals of the normal curve.

COMPARISON OF POWER FUNCTIONS FOR COMPLIANCE OFFICER'S TESTS WITH 1% AND 5% SIGNIFICANCE LEVELS

For the compliance officer, the PF curve gives the power (probability) that the test data will yield a decision for noncompliance when non-

compliance of a specified amount truly exists. Figure J-3 gives the PF curve for the Compliance Officer's Test at a 5% risk (significance) level. The criterion is that a citation should not be issued unless the 95% LCL for the employee exposure exceeds the standard. Since the probability of a type I error is 5%, can the employer state he will be incorrectly cited 5% of the time? Certainly not. Only if the true average employee exposure of the measured employee is just at or slightly below the standard is there a 5% chance of an incorrect citation and this probability rapidly drops to essentially zero for true average employee exposures under the standard. The term 5% risk level refers to the maximum risk of declaring noncompliance when the true average employee exposure is exactly equal to the standard. The term has no meaning elsewhere on the PF curve.

An example demonstrating the use of Figure J-3 would be a compliance officer obtaining two

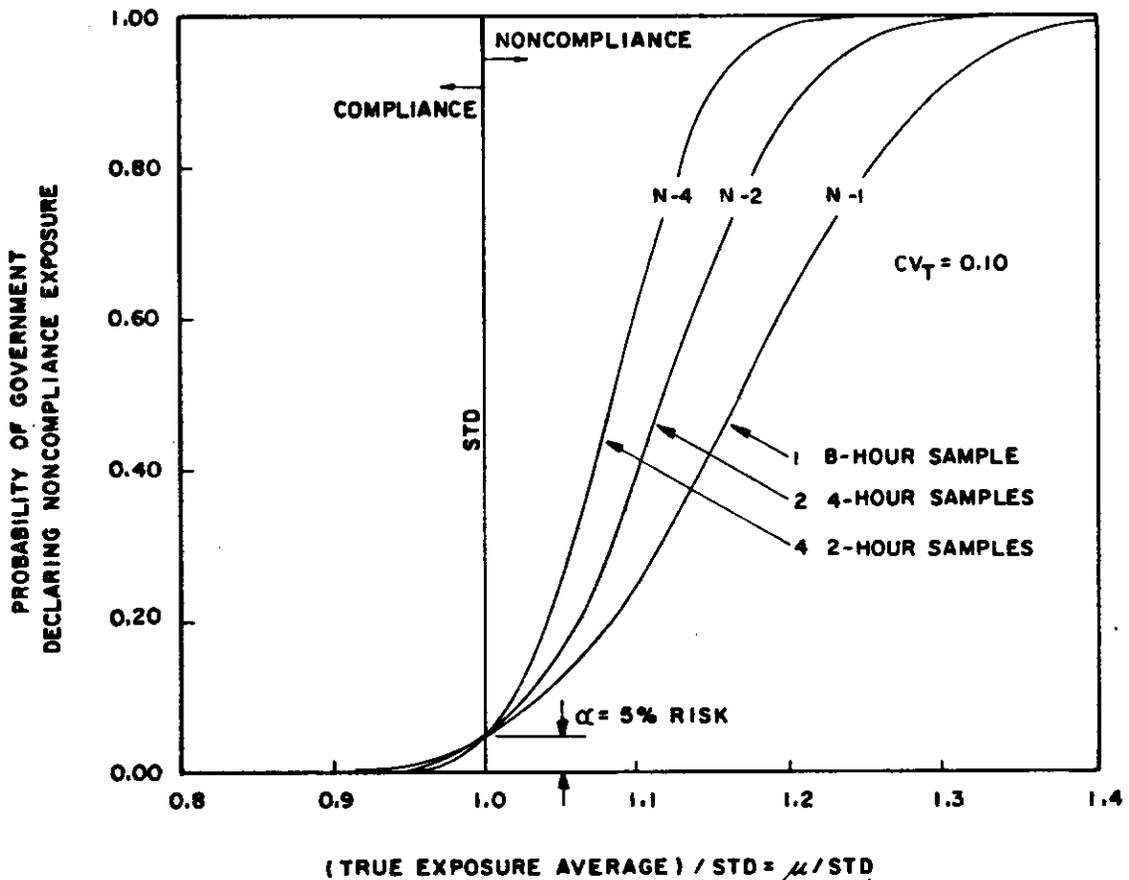


Figure J-3. Power function (PF) curve for one-sided Compliance Officer's Test (5% risk level) to detect noncompliance as given in sections 4.2.1 and 4.2.2. Calculated for sampling/analytical method with $CV_T=0.10$ (about $\pm 20\%$ accuracy at 95% confidence level).

consecutive 4-hour samples using a NIOSH method with $CV_T=10\%$. By the procedure of section 4.2.2, noncompliance should not be declared unless the standardized exposure measurement \bar{x} exceeded 1.116, or 11.6% above the standard. If the true standardized exposure average happened to be at 1.116, Figure J-3 shows there would be only a 50% chance of alleging noncompliance. This is because only half of the possible measurement values would exceed the true average and result in a declaration of noncompliance. The employee might believe this provides him with an adequate level of protection.

However, the employer could possibly argue that the choice by the government of a 5% risk level test would not provide him sufficient protection against an incorrect citation if the true average employee exposure (for one employee on one day) were at or slightly below the stand-

ard. The employer could propose that the government use a 1% risk level test, and Figure J-4 illustrates the effect of this proposal on the PF curve. The probability of a citation for a true case of noncompliance (where the true exposure average exceeds the standard) decreases markedly. For the previous example with a true standardized exposure average of 1.116, the probability of the compliance officer alleging noncompliance drops to 27% (from 50%) using the 1% risk level test. The true exposure average has to be 1.164 (16.4% above the standard) before there is a 50% chance of alleging noncompliance. Thus, when the employer's risk is decreased, the protection afforded the employee is markedly decreased.

The effect of sampling/analytical method accuracy on the PF curves is shown for the Compliance Officer's Test (5% risk level) by Figure J-3 ($CV_T=10\%$) and Figure J-6 (CV_T

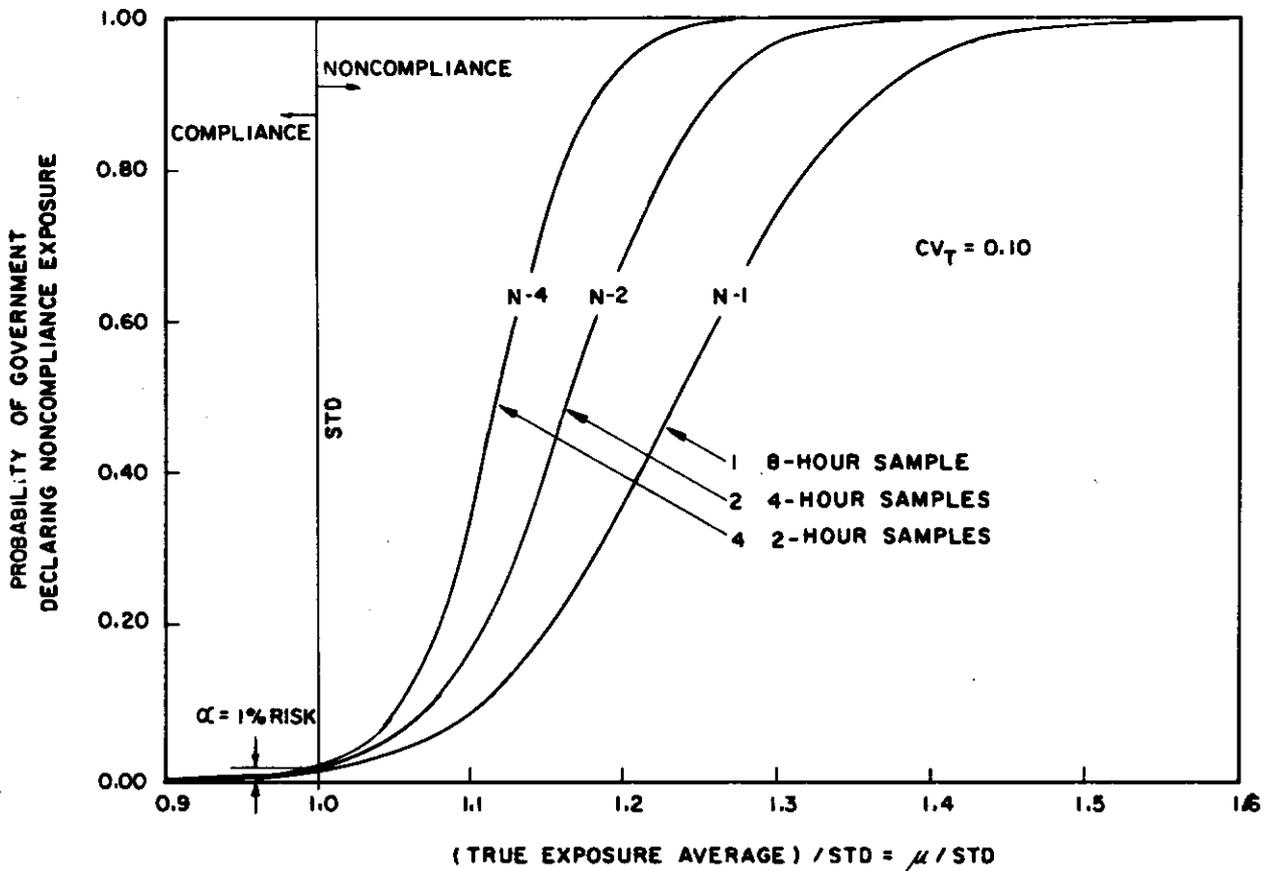


Figure J-4. Power function (PF) curve for one-sided Compliance Officer's Test (1% risk level) to detect noncompliance as given in sections 4.2.1 and 4.2.2. Calculated for sampling/analytical method with $CV_T=0.10$ (about $\pm 20\%$ accuracy at 95% confidence level).

=5%). The effect on the Employer's Test (5% risk level) is shown by Figure J-2 ($CV_T=10\%$) and Figure J-5 ($CV_T=5\%$).

In conclusion, we have seen the necessity for using statistical sampling plans and decision theory both in the monitoring of employee exposures and as part of the decision making processes regarding compliance or noncompliance with mandatory health exposure standards. The use of statistical tests means that maximum desired risk levels can be selected in advance and the burden of the sampling program minimized. The selection of a 5% risk level for both compliance and noncompliance tests is appropriate in that it protects both the employer and employee against unreasonable risk.

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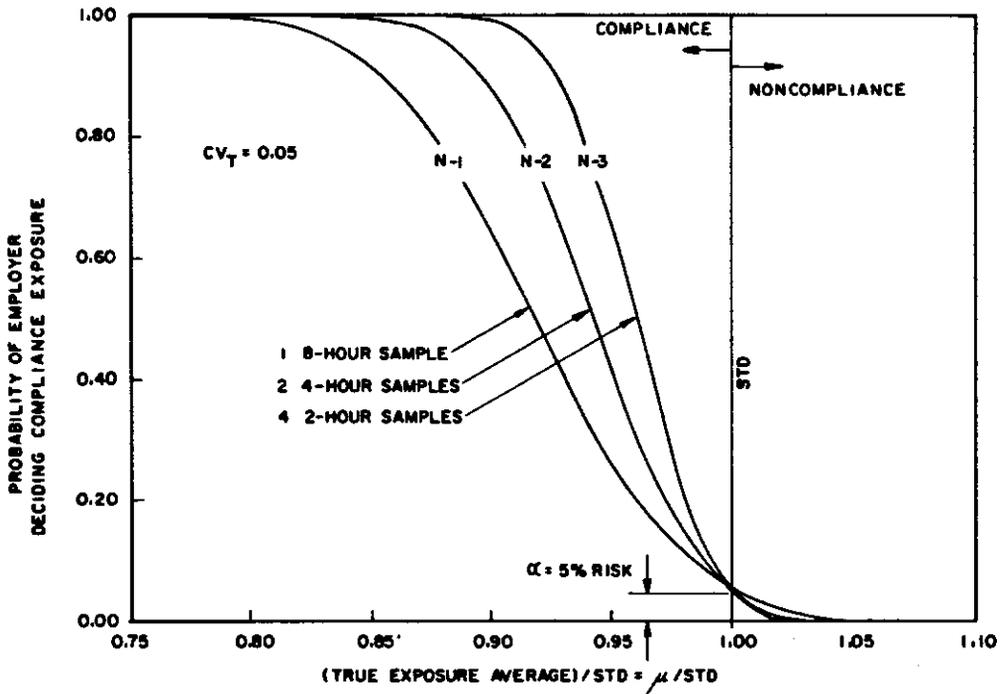


Figure J-5. Power function (PF) curve for one-sided Employer's Test (5% risk level) to ensure compliance as given in sections 4.2.1 and 4.2.2. Calculated for sampling/analytical method with $CV_T=0.05$ (about $\pm 10\%$ accuracy at 95% confidence level).

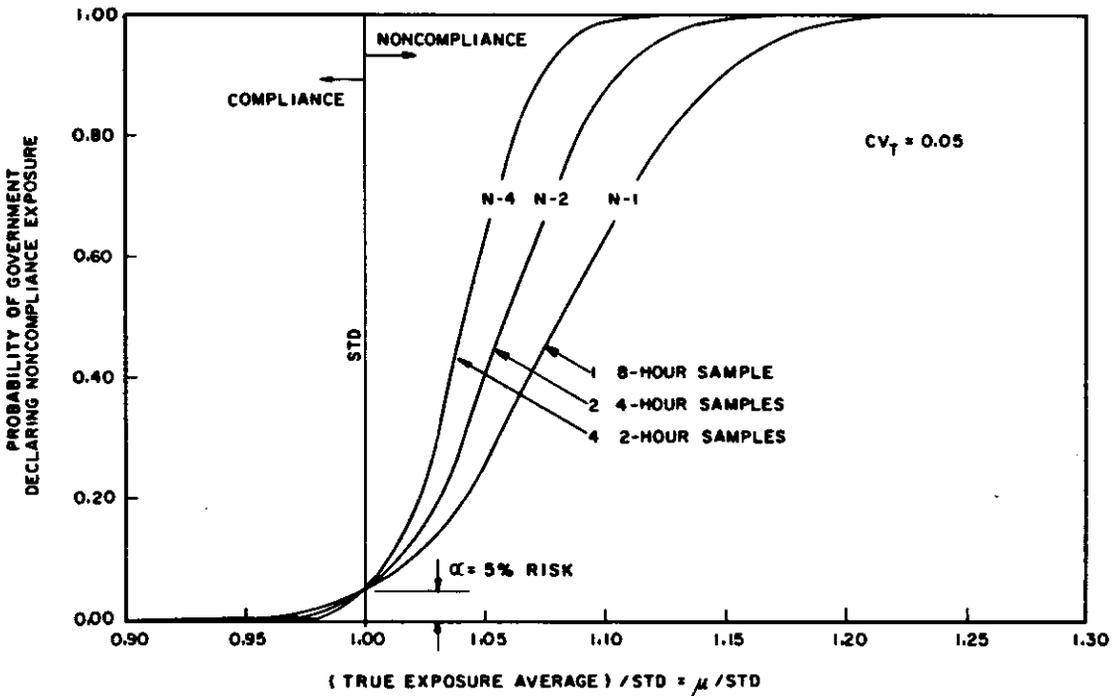


Figure J-6. Power function (PF) curve for one-sided Compliance Officer's Test (5% risk level) to detect noncompliance as given in sections 4.2.1 and 4.2.2. Calculated for sampling/analytical method with $CV_T=0.05$ (about $\pm 10\%$ accuracy at 95% confidence level).

TECHNICAL APPENDIX K*

STATISTICAL DECISION THEORY FOR CEILING EXPOSURE MEASUREMENTS

The problem in the ceiling decision procedure (section 4.3) is that given a set of samples of short (generally 15-minute) ceiling exposure measurements on any one day, an inference has to be made about the exposure during the sampled intervals and the exposure during the remaining unsampled intervals of that day.

DECISION ON THE EXPOSURE DURING THE SAMPLED INTERVALS

The decision about the exposure for the sampled intervals is made by using the one-sided confidence region for the highest observed exposure measurement. This confidence region is determined assuming that the random measurement errors are normally distributed with known standard deviation. This standard deviation is based on the coefficient of variation of the sampling/analytical procedure. If all the available samples indicate (with high confidence) that the exposure during the observed intervals is below the ceiling standard (*CSTD*), use the following procedure to make a statistical inference for the remaining unsampled intervals (potential measurements).

DECISION ON THE EXPOSURE DURING THE REMAINING INTERVALS

The problem can be stated as a test of the null hypothesis:

H_0 : The whole population of potential samples is below the ceiling standard (*CSTD*)

versus the alternative hypothesis:

H_1 : At least one of the potential samples could exceed the *CSTD*.

*The material in this appendix was developed by Systems Control, Incorporated and originally appeared in SCI Report #5119-1, pp. 17-20 (May 1975) produced under NIOSH Contract #CDC-99-74-75.

Assume the following set of ceiling measurements from a given day is available, each with a duration equal to the period for which the ceiling standard has been defined: $X_j, j=1, \dots, n$. Let

$$x_j = \frac{X_j}{CSTD}$$

be the standardized (with respect to the ceiling standard, *CSTD*) measurements.

These are short-term samples, and if they are not contiguous, it is assumed that they are independent, identically distributed, lognormal random variables. Furthermore, since only temporal variations are being considered, the random measurement error due to the sampling and analytical procedure will be neglected in this case.

The statistical model will be formulated in terms of the logarithms (base 10) of the standardized data. Therefore, let

$$y_j = \log x_j, j=1, \dots, n \quad (K-1)$$

To make a decision concerning an employee's ceiling level exposure, the following hypotheses must be tested with given maximum probabilities of error of type I and II.

$$H_0: y_i \leq 0 \text{ for all } i=n+1, \dots, N \quad (K-2)$$

versus

$$H_1: y_i > 0 \text{ for at least one } i, n+1 \leq i \leq N \quad (K-3)$$

where N is the size of the sample space. If the ceiling level standard is defined for 15-minute sampling intervals, then $N=32$ for an 8-hour day. H_0 is the compliance exposure decision,

and H_1 is the *noncompliance exposure* decision. If neither decision can be asserted with sufficiently high confidence, then a *possible over-exposure* classification is made.

The above hypothesis testing problem can be formulated in terms of a probability statement. Given the set of samples $y^n \triangleq \{y_1, \dots, y_n\}$, compute the probability of compliance.

$$P_c \triangleq \{y_{n+1} \leq 0, \dots, y_N \leq 0 | y^n\} \quad (K-4)$$

The probability density of one of the potential samples can be written as

$$p(y_k | y^n) = \int p(y_k, \mu, \sigma | y^n) d\mu d\sigma, k = n+1, \dots, N \quad (K-5)$$

where μ and σ are the (unknown) mean and standard deviation of y_j , $j=1, \dots, N$, and $p(y_k, \mu, \sigma | y^n)$ is the joint a posteriori density of y_k , μ , and σ given the observations y^n .

Using the fiducial distribution of μ (see reference K-1),

$$\mu \sim \mathcal{N}\left(\bar{y}, \frac{\sigma^2}{n}\right) \quad (K-6)$$

where $\mathcal{N}(a, b)$ is the normal density with mean a and variance b and

$$\bar{y} = \frac{1}{n} \left[\sum_{i=1}^n y_i \right] \quad (K-7)$$

Assuming for the present σ as known, one obtains from equation K-5

$$p(y_k | y^n) = \mathcal{N}\left[\bar{y}, \sigma^2 \left(1 + \frac{1}{n}\right)\right] \quad (K-8)$$

Then,

$$P\{y_k > 0 | y^n\} = \int_0^{\infty} \mathcal{N}\left[y_k; \bar{y}, \sigma^2 \left(1 + \frac{1}{n}\right)\right] dy_k \triangleq \beta \quad (K-9)$$

$k = n+1, \dots, N$

The probability of compliance (equation K-4) is now given by

$$P_c = \prod_{k=n+1}^N P\{y_k \leq 0\} \quad (K-10)$$

$$= \prod_{k=n+1}^N [1 - P\{y_k > 0\}]$$

Using the notation introduced in equation K-9 one has

$$P_c = (1 - \beta)^{N-n} \quad (K-11)$$

If $(N-n)\beta \ll 1$, then a good approximation for the above is

$$P_c \approx 1 - (N-n)\beta \quad (K-12)$$

The assumption of known σ is not totally justified. An approach that would account for this additional uncertainty could be developed along the lines of (K-2) using Bayesian arguments with diffuse priors. However, the complexity of the resulting procedure would prevent it from being implemented. The sample variance

$$s^2 = \frac{1}{n-1} \sum_{j=1}^n (y_j - \bar{y})^2 \quad (K-13)$$

is recommended for equation K-9 in place of σ^2 .

Equation K-11 indicates that if $N-n$ (number of unobserved intervals) is large, the probability of compliance P_c becomes small. There are more "chances" for at least one sample to exceed the standard. Therefore, the direct application of equation K-11 might be overly pessimistic.

This leads to the concept of expected number of peaks during a day. Suppose that a "biased" ceiling sample procedure was used to obtain a few random samples from expected "critical" intervals. From knowledge of the industrial process, suppose the number of remaining peaks during the day is available and equal to n' . Then the number of unsampled intervals in equation K-9 is taken as n' , rather than $N-n$. If all the n' peak intervals were sampled, there would be no need to go to the inference procedure for the unsampled intervals and the only test to be done would be the one described in the section on "Decision on the Exposure During the Sampled Intervals," above. Recall that the motivation for developing the inference procedures based upon samples from only a part of the workday stems from the basic objective of minimizing the employer's burden. Thus, if the available samples have been taken from known peaks and there are in addition n' unsampled expected peaks during the day, then

the decision (exposure classification) is made based upon

$$P_c = (1 - \beta)n' \quad (\text{K-14})$$

if the available samples do not indicate overexposure or exposure. If the probability of compliance P_c exceeds a present threshold — say 0.9 — the worker is classified as unexposed. On the other hand, if P_c is below another threshold — say 0.1 — then the worker can be classified as overexposed. Otherwise, the classification is “exposed.”

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TECHNICAL APPENDIX L

THE NEED FOR AN OCCUPATIONAL EXPOSURE MEASUREMENT ACTION LEVEL*

Some of the proposed OSHA standards define the *action level* as one-half the value of the *permissible exposure limit* currently found in Tables Z-1, Z-2, and Z-3 of 29 CFR 1910.1000. The *action level* is the point at which certain provisions of the proposed standards must be initiated, such as periodic employee exposure measurements, training of employees, and medical surveillance (if appropriate for the particular substance). These provisions are initiated if *single day exposure measurements* on an employee exceed the *action level*.

Section 6(b)(7) of the Occupational Safety and Health Act directs that, where appropriate, occupational health standards shall provide for monitoring or measuring employee exposure at such locations and intervals in such a manner as may be necessary for the protection of employees. NIOSH and OSHA recognized the need to designate an exposure measurement level at which these procedures become appropriate. The function of the action level is to designate this exposure measurement level.

The objective of this presentation is to explain the necessity for an employee exposure measurement action level and its relation to variations in the occupational environment.

Employee exposure monitoring programs are analogous to quality control and assurance programs used widely in industry. The daily average of concentrations that an employee is exposed to during his employment is very similar to a product off an assembly line. The assembly

line product and, by analogy, daily exposure averages are subject to

- random fluctuations in the process such as between employees or machines performing the same task;
- gradual trends toward an out-of-tolerance state of the process such as might be caused by machine tool wear; and
- sudden occurrence of defective parts due to drastic changes in the process.

There are also similarities in purpose between employee exposure monitoring programs and quality control programs (Table L-1).

Each of the factors in Table L-1 has been considered in the proposed OSHA standards. Two factors in particular (numbers 1 and 6) have special relevance to the action level concept: the *variations* in employees' daily exposures and *limiting the risk* (to a low probability) that an employee will be overexposed due to failure to detect days of high exposure.

The action level was set with the view that the employer should minimize the probability that even a very low percentage of actual daily employee exposure averages (8-hour time-weighted averages [TWA]) will exceed the standard. That is, the employer should monitor employees in such a fashion that he has a high degree of confidence that a very high percentage of actual daily exposures are below the standard. In statistical terms, the employer should try to attain 95% confidence that no more than 5% of employee days are over the standard.

It is important to realize that the employee's exposure concentration is not a fixed phenomenon. In statistical terms, the exposure concentrations fluctuate in a lognormal manner. First, the exposure concentrations are fluctu-

*This material was originally presented by Nelson A. Leidel at the OSHA Informal Public Hearing on Proposed Ketone Standards, Washington, D.C., September 4, 1975. The full NIOSH Technical Report is available as Reference L-2.

TABLE L-1. COMPARISON OF QUALITY CONTROL AND EMPLOYEE EXPOSURE MONITORING PROGRAMS

Quality control programs	Employee exposure monitoring programs
<p>1. Identify variation in product quality due to</p> <ul style="list-style-type: none"> —differences among machines; —difference among workers; —differences in raw materials or component parts; —differences in each of these factors over time. 	<p>1. Identify variation in measurements of employees' daily exposures due to</p> <ul style="list-style-type: none"> —differences in work techniques of individual employees (even in the same job category); —differences in the exposure concentrations during a day (reflected in grab samples); —differences in the average daily exposure concentrations between days; —differences due to random variations in sampling and analysis.
<p>2. Detect if a product is out of tolerance or a process is yielding unsatisfactory products.</p>	<p>2. Detect if any employee exposures exceed a permissible limit.</p>
<p>3. Institute sampling plans that furnish a maximum amount of protection against sampling errors with a minimum amount of inspection.</p>	<p>3. Institute a monitoring program that needs a minimum amount of sampling for a maximum amount of protection against exposure measurement errors.</p>
<p>4. Institute methods that indicate quickly when something is wrong or about to go wrong with the process before defective products are made.</p>	<p>4. Institute exposure measurement plans that indicate when the occupational exposures are hazardous or approaching hazardous levels before overexposures occur.</p>
<p>5. Periodically sample from a production process.</p>	<p>5. Periodically measure an employee's daily exposure.</p>
<p>6. Limit to a low probability that a bad lot (one containing defectives) will be accepted on the "luck of the draw" inherent in the sampling process.</p>	<p>6. When not all exposure days are measured, limit, to a low degree, an employee's probability of overexposure caused by failure to detect high exposure days.</p>
<p>7. Detect and attempt to correct sources of process variation that lead to defects.</p>	<p>7. Detect and try to eliminate sources of high employee exposures.</p>

ating over the 8-hour period of the TWA exposure measurement. Breathing zone grab samples (samples of less than about 30 minutes' duration — typically, only a few minutes) tend to reflect the environmental variation within a day so that grab sample results have relatively high variability. However, this variation in the sample results can be eliminated by using a full period sampling strategy as discussed by Leidel and Busch (L-1) and Chapter 3. Second, the

day-to-day variation of the true 8-hour TWA exposures is also lognormally distributed. It is this day-to-day variation that creates a need for an action level based on only one day of required exposure measurement. The one day's measurement is used to draw conclusions regarding compliance on unmeasured days and is the sole basis for deciding whether further measurements should be made on a particular employee.

Environmental variation is expressed by the geometric standard deviation (GSD). A GSD of 1.0 represents absolutely no variation in the environment whereas GSD's of 2.0 and above represent relatively high variation. When based on analysis of gas, vapor, and particulate data, it was concluded that very few industrial operations have day-to-day environmental GSD's less than about 1.2.

If one particular day's exposure measurement showed an 8-hour employee exposure average less than the standard, we could not conclude that all other days' exposures are less than the standard. This is because the true daily exposure average on one day was drawn from a log-normal distribution of all other true daily exposures over a period of time. The long term exposure average is assumed to remain stable, but the sample on a particular day might have come from a low portion of the distribution. Even though the one daily exposure average is less than the standard, there is a risk of other daily averages exceeding the standard.

A statistical model was developed that showed the relation of the probability (risk) that at

least a given percentage of true daily exposure averages will exceed the standard, as a function of

- 8-hour TWA employee exposure measurement on one day as a fraction of the standard, and
- day-to-day environmental variation of true daily exposure averages (GSD), and
- precision and accuracy of the sampling and analytical method used in the measurement process.

The graphic results of this model are shown in Figure L-1. For the graphic presentation, a 10% sampling and analytical coefficient of variation (CV_T) was assumed. This corresponds to an accuracy for the measurement method of about 20% at a confidence level of 95%. However, the curves are labeled for "pure" day-to-day variation. It is very important to realize that the random measurement errors due to the sampling and analytical procedure make a very minor contribution to the calculated employee risk of having a given percentage of true daily averages exceed the standard. This calculated risk is almost solely a function of the day-to-day variation.

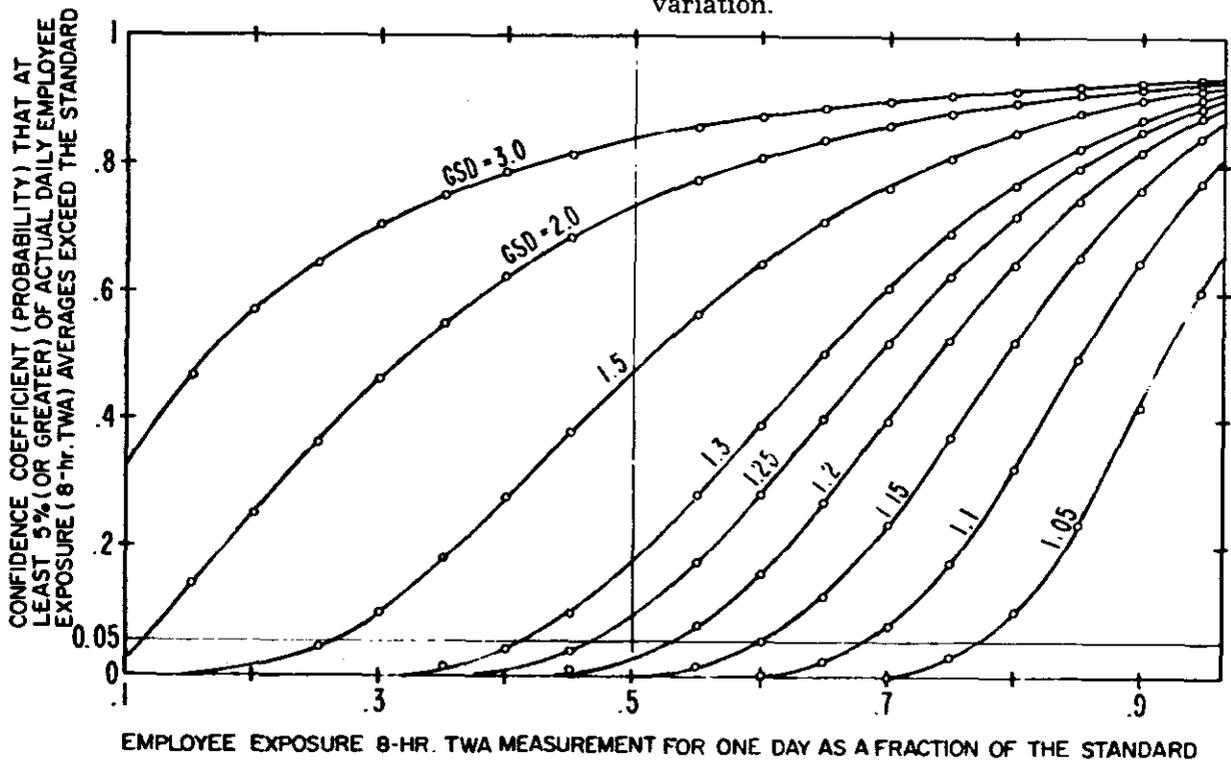


Figure L-1. Employee overexposure risk curves for one 8-hour TWA exposure measurement.

Thus, Figure L-1 shows the probability that at least 5% of an employee's unmeasured true daily exposure averages will exceed the standard given the fact that one day's measurement happened to fall below the standard. Declaring an employee as *safe* and never sampling again because one day's exposure measurement fell below the standard would be analogous to accepting a factory's entire production on the basis of only one tested product. That is why an action level of one-half the standard is necessary as a "trigger" to ensure further sampling of an employee. An exposure measurement as low as one-half the standard indicates sufficient probability of an employee's exposure exceeding the standard on other days so that additional measurements are needed to ensure adequate protection of that employee.

Figure L-1 shows that employees with day-to-day exposure average GSD's of less than about 1.22 (combined with a sampling/analytical CV_T of 10%) have less than 5% probability of having 5% of their true daily exposures exceed the standard on unmeasured days. It is likely that very few day-to-day GSD's are less than 1.22. Note that if one measured daily exposure average is at one-half the standard, then the following much higher probabilities exist that at least 5% of the unmeasured true daily averages exceed the standard:

<i>Day-to-day variation</i>	<i>Probability, %</i>
<u>GSD = 1.3</u>	<u>17</u>
= 1.5	47
= 2.0	72
= 3.0	83

Finally, it should be noted that the above considerations concerning the stability of the distribution of true daily exposures the employee encounters are very conservative. Only random variations are considered. We have not considered unpredictable upward trends or sudden increases in daily exposures caused by changes in the employee's environment, such as closed plant doors and windows in cold seasons, decreased efficiency of or failure of engineering control measures (e.g., ventilation systems), or changed production processes leading to increased exposure.

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TECHNICAL APPENDIX M*

NORMAL AND LOGNORMAL FREQUENCY DISTRIBUTIONS

The statistical methods discussed in this manual assume that concentrations in random occupational environmental samples are lognormally and independently distributed both within any particular workshift and over many daily exposure averages. Additionally, it is assumed that the sampling and analytical errors of an industrial hygiene measurement sample are normally and independently distributed. The technical reasons for the choice of these two distributions for modeling our data distributions are given below. There is nothing sacred about the choice of these distribution models. They were chosen because they occur very frequently in industrial hygiene applications, and they are easy to use because their properties have been thoroughly investigated. The empirical observation that the data usually are well-fitted by the normal and lognormal models is no guarantee that all data fit these models. If there is any doubt about the appropriate application of the normal or lognormal model, the first step in the data analysis should be to sketch a distribution histogram or use probability paper as discussed in Technical Appendix I. Also refer to Technical Appendix I for examples of data that might not be adequately described by the lognormal model.

Before sample data can be statistically analyzed, we must have knowledge of the frequency distribution of the results or some assumptions must be made. Roach (M-2-M-4) and Kerr (M-5) have assumed that environmental data are normally distributed. However, it is well established (M-6-M-9) that most com-

munity air pollution environmental data are better described by a lognormal distribution. That is, the logarithms (either base e or base 10) of the data are approximately normally distributed. Most importantly, Breslin et al. (M-10), Sherwood (M-11, M-12), Jones and Brief (M-13), Gale (M-14, M-15), Coenen (M-16, M-17), Hounam (M-18), and Juda and Budzinski (M-19, M-20) have shown that occupational environmental data from both open air and confined work spaces for both short (seconds) and long (days) time periods are lognormally distributed.

What are the differences between normally and lognormally distributed data? First, it should be remembered that a "normal" distribution is completely determined by the arithmetic mean μ and the standard deviation σ of the distribution. On the other hand, a lognormal distribution is completely determined by the median or geometric mean (GM) and the geometric standard deviation (GSD). For lognormally distributed data, a logarithmic transformation of the original data is normally distributed. The GM and GSD of the lognormal distribution are the antilogs of the mean and standard deviation of the logarithmic transformation. Normally distributed data have a symmetrical distribution curve whereas lognormally distributed environmental data are generally positively skewed (long "tail" to the right indicating a larger probability of very large concentrations when compared with a lower probability expected of normally distributed data). Figure M-1 compares a lognormal distribution to a normal distribution with the same arithmetic mean μ and standard deviation σ . The conditions conducive to (but not all necessary for) the occurrence of lognormal distributions are found in occupational

*This material in part was originally presented in Leidel and Busch, *Exposure Measurement Action Level and Occupational Exposure Variability* (NIOSH Technical Information, HEW Publication No. (NIOSH) 76-131, Cincinnati, Ohio, December 1975) and Reference M-1.

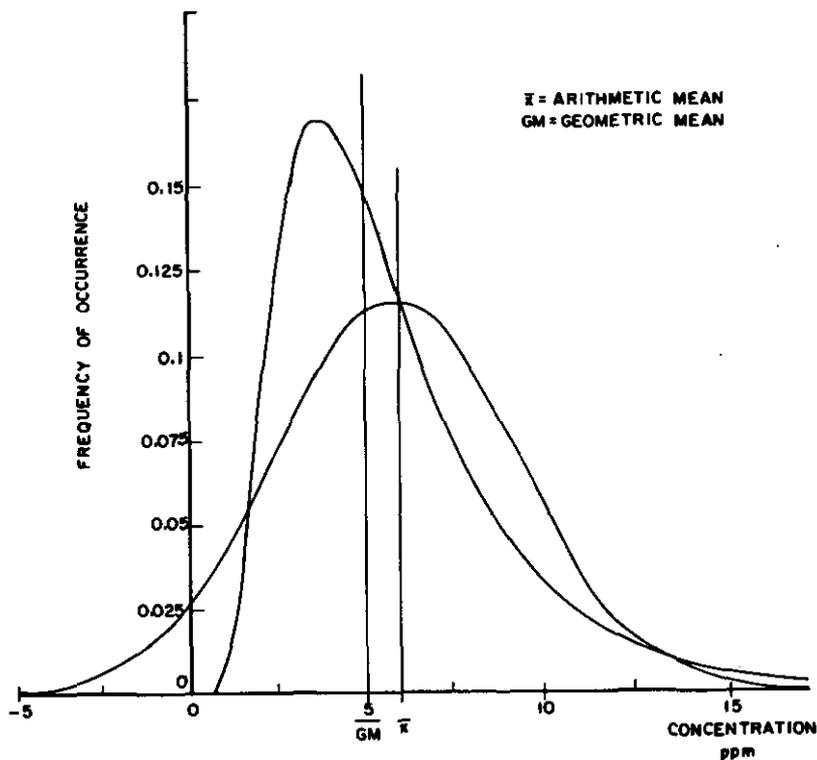


Figure M-1. Lognormal and normal distributions with the same arithmetic mean and standard deviation.

environmental data (M-16). These conditions are that

- the concentrations cover a wide range of values, often several orders of magnitude,
- the concentrations lie close to a physical limit (zero concentration),
- the variation of the measured concentration is of the order of the size of the measured concentration, and
- a finite probability exists of very large values (or data "spikes") occurring.

The variation of occupational environmental data (differences between repeated measurements at the same site) can usually be broken into three major components: random errors of the sampling method; random errors of the analytical method; and variation of the environment with time. The first two components of the variation are usually known in advance and are approximately normally distributed. The environmental fluctuations of a contaminant in a plant, however, usually greatly exceed the variation of known instruments (often by factors of 10 or 20). The above components of variation were discussed in an article by LeClare et al. (M-21).

When several samples are taken in a plant to determine the average concentration of the contaminant and estimate the average exposure of an employee, the lognormal distribution should be assumed. However, the normal distribution may be used in the special cases of taking a sample to check compliance with a ceiling standard, and taking a sample (or samples) for the entire time period for which the standard is defined. In these cases, the entire time interval of interest is represented in the sample, with only normally distributed sampling and analytical variations affecting the measurement.

The relative variation of a normal distribution (such as the random errors of the sampling and analytical procedures) is commonly measured by the coefficient of variation (CV). The CV is also known as the relative standard deviation. The CV is a useful index of dispersion in that limits consisting of the true mean of a set of data, plus or minus twice the CV, will contain about 95% of the data measurements. Thus, if an analytical procedure with a CV of 10% is used to repeatedly measure some nonvarying physical property (such as the concentration of a

chemical in a beaker of solution), then about 95% of the measurements will fall within plus or minus 20% (2 times the CV) of the true concentration.

Unfortunately, the property we are trying to measure — the employee's exposure concentration — is not a fixed physical property. The exposure concentrations are fluctuating in a lognormal manner. First, they are fluctuating over the 8-hour period of the TWA exposure measurement. Breathing zone grab samples (samples of less than about 30 minutes' duration, typically only a few minutes) tend to reflect the environmental variation within a day so that grab sample results have relatively high variation. However, this variation in the sample results can be eliminated by going to a full period sampling strategy as discussed by Leidel and Busch (M-1). Second, the day-to-day variation of the true 8-hour TWA exposures is also lognormally distributed.

Environmental variation is expressed by the GSD. A GSD of 1.0 represents absolutely no variation in the environment. GSD's of 2.0 and

above represent relatively high variation. Hald (M-22) states that the shape of lognormal distributions with low variations, such as those with GSD's less than about 1.4, roughly approximate normal distribution shapes. For this range of GSD's, there is a rough equivalence between the quantity $(GSD-1)$ and the CV, as follows:

<u>GSD</u>	<u>(GSD-1)</u>	<u>CV</u>
1.05	0.05	0.049
1.10	0.10	0.096
1.20	0.20	0.18
1.30	0.30	0.27
1.40	0.40	0.35

For those interested in a detailed study of the lognormal distribution, Aitchinson and Brown (M-23) is an excellent reference. Figure M-2 shows four different lognormal distributions that share a common arithmetic mean of 10 ppm. Four different variations are shown with GSD's of 1.2, 1.5, 2.0, and 3.0.

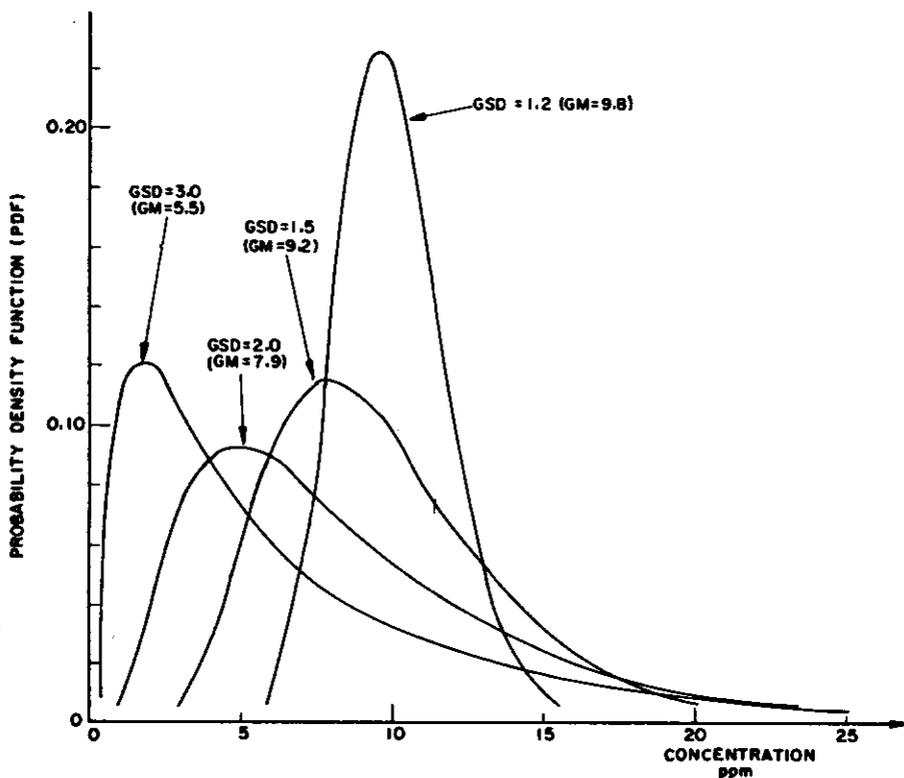


Figure M-2. Lognormal distributions for arithmetic mean concentration of 10 ppm.

CONVERSION FORMULAS FOR A LOGNORMAL FREQUENCY DISTRIBUTION

If the variable $(\ln x)$ is normally distributed (the variable x has a lognormal distribution), we can define

μ = true arithmetic mean of x -distribution

σ = true standard deviation of x -distribution

μ_l = true arithmetic mean of $(\ln x)$ values

σ_l = true standard deviation of $(\ln x)$ values

GM = geometric mean of x -distribution

GSD = geometric standard deviation = $\exp(\sigma_l)$ where $(\ln x)$ was used to calculate σ_l

$GSD = \text{antilog}_{10}(\sigma_l)$ where $(\log_{10} x)$ was used. The conversion relations between the above six parameters are given in Table M-1.

Notes:

1. The relations apply *only* to the true parameter of the parent distribution. They *should not* be used for parameters of a sample except as a very rough approximation.

2. The GM and GSD are used to describe parameters of either a sample or the parent distribution, but they cannot be used in the relations unless they are calculated from the true parent distribution.

3. The GSD of the x -distribution is the same regardless of whether base 10 or base e logarithms were used to calculate σ_e .

TABLE M-1. CONVERSION RELATIONS BETWEEN LOGARITHMIC PARAMETERS AND ARITHMETIC PARAMETERS OF A LOGNORMAL DISTRIBUTION

Given	To obtain	Use
μ_l	$GM =$	$\exp(\mu_l)$
μ, σ	$GM =$	$\mu^2 / \sqrt{\mu^2 + \sigma^2}$
σ_l	$GSD =$	$\exp(\sigma_l)$
μ, σ	$GSD =$	$\exp \sqrt{\ln \left(1 + \frac{\sigma^2}{\mu^2}\right)}$
μ_l, σ_l	$\mu =$	$\exp \left(\mu_l + \frac{1}{2} \sigma_l^2\right)$
GM, σ_l	$\mu =$	$(GM) \exp \left(\frac{1}{2} \sigma_l^2\right)$
μ_l, σ_l	$\sigma =$	$\sqrt{\frac{[\exp(2\mu_l + \sigma_l^2)] [\exp(\sigma_l^2) - 1]}{GM^2}}$
GM, σ_l	$\sigma =$	$\sqrt{\frac{[\exp(\sigma_l^2)] [\exp(\sigma_l^2) - 1]}{(GM)^2}}$
GM	$\mu_l =$	$\ln(GM)$
μ, σ_l	$\mu_l =$	$\ln \mu - \frac{1}{2} \sigma_l^2$
GSD	$\sigma_l =$	$\ln(GSD)$
μ, σ	$\sigma_l =$	$\sqrt{\ln \left(1 + \frac{\sigma^2}{\mu^2}\right)}$
μ_l, σ_l	<i>mode</i>	$\exp(\mu_l - \sigma_l^2) = \text{most frequent value}$

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TECHNICAL APPENDIX N

GUIDELINES FOR SELECTING AND USING AN INDUSTRIAL HYGIENE CONSULTANT

KNOWING WHEN A CONSULTANT IS NEEDED

Having read the previous chapters, you should have a feeling for the situations that you can deal with on your own. If you are still unsure of the solution or if preliminary control measures have proved unsatisfactory, it may be time to consider the use of a consultant. Industrial hygiene consultants are primarily used to accomplish two major objectives. The first is to identify and evaluate potential health and safety hazards to workers in the occupational environment. The second objective is to design and evaluate the effectiveness of controls to protect the workers in the workplace. The material and guidelines of this appendix are based on material presented in Chapter 6 of the *Industrial Noise Control Manual (N-1)*. That manual should be referred to for guidelines for selecting a noise control engineering consultant.

Even though you may be familiar with the chemicals and processes used in your plant or shop, you may not believe you have the background or training to evaluate their health effects and recognize potentially hazardous exposure situations. Competent industrial hygiene consultants are able to perform these tasks because of their training and experience. Also, consultants can efficiently and economically evaluate the size of employee exposures, because of their knowledge of the proper sampling equipment and analytical procedures required.

Consultants can also recommend whether or not control measures are required and the alternatives available. They can design, supervise the installation of, and evaluate the effectiveness of control measures. Alternatives include substituting less toxic materials and changing the process, engineering controls, administrative

controls, and personal controls such as respirators. Also, if you have installed control measures that don't work, you may have to use a consultant to resolve the problem. Although this may be a painful decision, it should occur only once. You should document the situation thoroughly and use the consultant to supply information on what went wrong, either through improper design, improper installation, or both.

Consultants can be used to keep you aware of the requirements of current Federal and state regulations in the area of occupational safety and health. They can inform you when medical examinations of your employees may be recommended or required by regulation. They should be able to recommend appropriate physicians or clinics in your area specializing in occupational medicine. The consultant can play a valuable role in providing the examining physician with information on the occupational exposures of each employee examined and alert the physician to particular medical tests either recommended or required by regulations. Consultants can also design employee training programs and provide information for them. A consultant can serve as an expert witness if you are involved in a lawsuit and data must be obtained, interpreted, and presented by a disinterested third party.

SELECTION OF A CONSULTANT

Now that you have decided to obtain a consultant, how do you proceed? You should first be aware that currently any person can legally offer services as an industrial hygiene consultant. Consequently, it is up to you to avoid those who are unsuitable because of lack of training, inexperience, or incompetence.

Individuals or firms billing themselves as industrial hygiene consultants can be broadly classified according to whether they recommend a particular monitoring procedure, medical examination service, or control process, or are independent consultants.

These product-oriented individuals or firms vary in their backgrounds from nontechnical product salespersons to experienced industrial hygiene professionals. Special interest consultants, who are most commonly identified by the degree of their association with manufacturing or retail sales of occupational health and safety products, should be used only if, by the use of the techniques described in the previous chapters, you have satisfied yourself that you know what sampling strategy or control procedure is applicable to your situation. In this case, "consulting" consists mainly of recommending appropriate exposure monitoring equipment and analytical facilities. This type of consultation may include assistance in soliciting proposals for the design and installation of control equipment, such as ventilation control systems or respirators. The main problem remaining is to write the contract in such a way that you are guaranteed (to the extent possible) a solution to your problem at a reasonable cost. The advantage of using this group directly is that you avoid consultant costs and pay only for the product or service. In effect, you are acting as your own consultant. The disadvantage in dealing with a product-oriented consultant is that a costly mistake, more expensive than the independent consultant's fees, is more likely since these consultants may not consider all options available. Examples abound of cases where thousands of dollars were spent in purchasing a particular type of monitoring equipment or in implementing a particular control system, only to discover that the desired results were not obtained.

If there are any doubts in your mind as to the proper method for solving your problem, then an independent consultant (one free from ties to a particular service or line of products) should be called in. It is this type of industrial hygiene consultant that will be discussed for the remainder of this appendix.

There are several sources one can go to for information and names of consultants available locally. The National Institute for Occupational

Safety and Health (NIOSH) has 10 regional offices across the country located in large cities. Their phone numbers are listed under "United States Government, Department of Health, Education, and Welfare." NIOSH regional offices usually have lists of consultants in their region (consisting of several states). NIOSH offices can provide technical information on a wide range of occupational safety and health topics. The Occupational Safety and Health Administration (OSHA) has both regional offices and several area offices in each region. OSHA office phone numbers are listed under "United States Government, Department of Labor." OSHA offices can also provide technical information particularly regarding Federal occupational safety and health standards. OSHA offices are particularly valuable in assisting in the determination of what standards may be applicable to your firm and their proper interpretation.

Other sources of information are the professional associations and public service organizations related to occupational safety and health. Three national groups are the American Industrial Hygiene Association (AIHA), American Society of Safety Engineers (ASSE), and the National Safety Council (NSC). These three have local chapters, sections, or offices in major cities which are a source of information and assistance. The AIHA publication *American Industrial Hygiene Association Journal* contains a list of industrial hygiene consultants in several issues each year.

Additional sources are a little more difficult to pursue. Useful information may be found in the Yellow Pages of your phone book. The headings to look under are Safety Consultants, Safety Equipment and Clothing Suppliers, Air Pollution Control, and so on. Many insurance companies now have loss prevention programs that employ industrial hygienists. Make inquiries of your present insurer and perhaps compare the services they offer to those of other insurance companies. Finally, there may be a university or college in your area that has an environmental health program. Generally their staff professionals are available for consultation.

GUIDELINE QUESTIONS TO ASK PROSPECTIVE CONSULTANTS

The best protection against an incompetent

consultant is to question the prospective consultant yourself. A series of questions is given below. They should not be given equal weight since some are minor in importance. (The list is organized roughly in descending order of importance.)

EXPERIENCE

1. For how many years have you been professionally active in industrial hygiene?
2. Please supply a list of recent clients that you have served, preferably in my geographical area, and on problems similar to those in which I am interested. Are you retained by any clients on a continuing basis? (Be sure to call a few of these references to obtain their opinion on the consultant's services.)
3. What teaching have you done or training have you had in industrial hygiene? What groups were involved: university, industry, trade associations, civic groups, engineers, symposia?

CONSULTATION STATUS

1. Are you now an independent consultant? For how many years? Full time or part time?
2. If part time:
 - a. Who is your chief employer or in what other business ventures are you involved?
 - b. Is your employer aware and does he approve of your part time activity as an industrial hygiene consultant?
 - c. May we contact your employer concerning you?
 - d. What restrictions does your employer place on you as a part time consultant?
3. Are you associated with the manufacture or sale of a product that could create a conflict of interest in your activities as a consultant?

EDUCATION

1. What schools did you attend and what courses did you take related to industrial hygiene?
2. What degrees did you receive and when?
3. What special conferences, seminars, symposia, or short courses have you attended (especially recently) to stay current with industrial hygiene technical information and governmental regulations?

4. What other sources of information do you use to stay current with the field of industrial hygiene?

PROFESSIONAL AFFILIATIONS

1. What professional associations do you belong to? (Representative ones are the American Industrial Hygiene Association, American Conference of Governmental Industrial Hygienists, American Society of Safety Engineers.) What is your present grade of membership and length of time in that grade for each association?
2. Are you certified by any of the following?
 - a. American Board of Industrial Hygiene (specify area of certification)
 - b. Board of Certified Safety Professionals
 - c. Environmental Engineering Intersociety Board (as an industrial hygiene engineer)
3. Are you a registered professional engineer? In what states and disciplines?
4. Of what professional engineer associations are you or your firm a member?
5. Of what trade associations, chambers of commerce, or similar business groups are you or your firm a member?

SPECIAL CAPABILITIES

1. In what areas of industrial hygiene do you specialize?
 - Comprehensive plant studies and/or analyses
 - Ventilation
 - Noise control
 - Audiometry
 - Biological monitoring
 - Heat stress
 - Ergonomics
 - Occupational medicine
 - Safety
 - Product safety and labeling
 - Radiological control
 - Training instruction
 - Air pollution
 - Meteorology
 - Waste disposal
 - Water pollution
2. What equipment do you have for conducting industrial hygiene evaluations in my plant or shop?
3. What laboratories do you use for the analysis of your exposure measurement samples? Are they accredited by the American In-

dustrial Hygiene Association? Do they participate in the NIOSH Proficiency Analytical Testing Program (PAT) and for what materials? (The AIHA Journal periodically publishes a list of accredited laboratories.)

4. What equipment do you have for calibrating test apparatus such as pumps and direct-reading instruments? Do you have a calibration program for your equipment?
5. Can you refer me to a physician or clinic capable of doing preplacement examinations, periodic examinations, or diagnostic examinations of my employees if these may be required? Do you have any business connection with these individuals or firms?
6. Can you refer me to engineering firms capable of installing controls such as local exhaust ventilation systems if these may be necessary? Do you have any business connection with these firms?
7. Can you refer me to appropriate safety equipment supplies if personal protective equipment is necessary for any of my employees? Do you have any business connection with these firms?
8. Can you serve as an expert witness, either for your client or as a friend of the court? What experience have you had as an expert witness?

BUSINESS PRACTICES

1. Please indicate your fee structure. Do you work by hourly charges, estimates for the total job, retainer charges, or any of these?
2. In your charges, how do you treat such expenses as travel, subsistence, shipping, report reproduction, and computer time?
3. Can you supply a list of typical laboratory analytical fees?
4. If you use a contract form, please supply an example.
5. What insurance and bonding do you have?
6. What statements do you have in your contracts covering commercial security, liability, and patent rights?
7. What restrictions are there on the use of your name in our reports, in litigation, or in advertisements?
8. What is the character and extent of reports that you prepare? Can you supply an example?
9. What facilities do you have for producing design drawings for control systems that

may be necessary?

10. What is the size of your staff? What are their qualifications? Who will be working on this project?
11. Do you have branch offices? Where?
12. Are you operating as an individual, partnership, or corporation?

THE PROPOSAL

Once you have selected a consultant, you can arrange to obtain his services in several ways. A verbal commitment is sometimes all that is necessary. However, you may wish to request a written proposal that spells out the steps to be taken in the solution of your problem.

Often, in a larger job, proposals from several points of view are evaluated and used as one of the bases for the final selection of the consultant. In this case, answers to pertinent questions in the preceding section may be sought in the proposal rather than in the interview. If so, evaluation of the proposal from this point of view is self-evident from the above discussion. If the questions you are interested in are not answered to your satisfaction, don't hesitate to ask for further clarification. In the discussion below, we are concerned with the section of the proposal that outlines the consultant's approach to your problem.

Aside from background qualifications of the consultant, the proposal should answer the questions:

1. How much is the service going to cost? Smaller jobs are often bid on an hourly basis, with a minimum of one-half day's work, plus direct expenses commonly specified. Larger jobs are usually bid at a fixed amount, based on the work steps described.
2. What is the consultant going to do? The answer to this question may range all the way from a simple agreement to study the problem to a comprehensive step-by-step plan to solve it.
3. What will be the end result? The answer to this question is all too often not clearly understood; the result is usually a report that specifies the consultant's recommendation. If you do not want to pay for the preparation of a written report, and a verbal one will do, specify this in advance. Since recommendations often call for construction to be carried out by others, whose

work is not subject to the consultant's control, results can usually not be guaranteed. Rather, an estimate of the exposure control to be attained is all that can be expected. If the consultant is to provide drawings from which the contractor will work, one must specify sketches or finished drawings. Generally, sketches are sufficient. If special materials are required, the consultant should agree to specify alternative selections, if possible. If you want a guaranteed result, experimental work will usually be necessary.

OTHER SERVICES

If you wish, the consultant can also monitor construction to determine compliance with specifications. The consultant can also measure after installation to confirm predictions and supply oral briefings as needed.

If the consultant is to serve as an expert witness for you, you will find that he is not automatically on your side. Rather, he is more like a friend of the court, devoted to bringing out the facts he has developed, with careful separation of fact from expert opinion. Complete frankness is needed if you want to avoid un-

pleasant surprises. For example, the consultant may be asked by the opposing attorney for a copy of his report to you. Thus, the report should be prepared with this possibility in mind.

If the consultant is retained to develop a specific control device for you, work out an agreement on patent rights. Ordinarily the patent is assigned to the client, with perhaps a royalty arrangement for the inventor.

For many situations, the consultant will need photographs and plans of machines and shop layout for his evaluation. Permission to obtain these can be granted in a manner consistent with your industrial security system.

The comments in this chapter should be read with the understanding that, where legal aspects are involved, appropriate legal counsel will be obtained to work with you and your consultant.

REFERENCES

- N-1. Salmon, V., J. S. Mills, and A. C. Petersen: Industrial Noise Control Manual, NIOSH Technical Information, HEW Pub. No. (NIOSH) 75-183, 1975. Available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402 as GPO #1733-00073.