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INTERPRETATION AND USE OF OCCUPATIONAL EXPOSURE LIMITS FOR CHRONIC DISEASE AGENTS

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Monson[1] recommended that the "role of the occupational epidemiologist must evolve into that of a person who assists in the setting of standards of exposure rather than that of a person who measures adverse effects of exposure." Burke[2] expressed similar concerns in discussing the role of epidemiology in developing federal, state, and local exposure limits: "[E]pidemiology is currently playing an increasing role in contemporary regulatory issues. . . . results of epidemiologic studies are being used by regulators to guide decisions. Shouldn't epidemiologists participate in determining how their data are applied?"

Monson and Burke suggest that occupational epidemiologists become active participants in the risk assessment process. After all, who knows the strengths and weaknesses of a study better than the occupational epidemiologist? Furthermore, exposure-response studies are rarely done out of mere scientific curiosity. Usually there is strong evidence that a substance causes one or more diseases, and it is desirable to quantify the risk or likelihood of developing such diseases in response to average or cumulative exposure or some other valid measure of exposure. The researcher knows and, in fact, expects that eventually a risk assessor will try to apply the study results in some practical, useful sense. Consequently, epidemiologists should be advocates of their research; that is, effective risk communicators who transmit their results and recommendations to risk assessors and risk managers, especially if their work reliably suggests that a current occupational exposure limit (OEL) is inadequate to the

task of protecting exposed workers. But first, it is essential to understand how OELs are used by company-level risk managers—industrial hygienists[3]—to assess and control occupational exposures.

This chapter discusses occupational exposure limits (OELs) for chronic disease agents both as a product of occupational exposure risk assessment and as an essential component of occupational exposure risk management.[4] Topics include:

- the OEL concept as an essential link to occupational epidemiology
- how OELs are used as a tool in occupational exposure (risk) management
- the process of setting an OEL

Along the way several themes should emerge:

- An OEL minimally consists of three components: concentration, averaging time, and target (usually the individual worker). Changing any component results in a modified OEL, designated as OEL′ (pronounced *OEL prime*). The OEL can be modified in many ways such that the resulting OEL′ will not provide the same level of protection as the original OEL.
- An OEL for chronic disease agents is often based on a long-term, working-lifetime mean exposure that is perceived as acceptable for groups of workers. However, the OEL is defined as an upper limit for each single-shift TWA exposure. This is the only practical way of ensuring that the true long-term, working-lifetime mean exposure of each employee is maintained at protective levels and also provides a practical means of accounting for the uncertainty in the risk assessment that led to the OEL.
- Once an OEL is established, exposure (risk) management should be viewed as a quality control problem: the distribution of exposures for each worker should be controlled so that exposures rarely exceed the "upper control limit" (i.e., the OEL).
- The measurement and control of occupational exposures are similar in concept to the medical management of nonoccupational risk factors, such as elevated cholesterol. Consequently, those charged with risk assessment (i.e., occupational exposure management) responsibilities in each company should focus on ensuring that risk to each employee is continually controlled. This requires monitoring at regular intervals.

This chapter frequently refers to risk assessors and risk managers— terms that are sometimes used interchangeably or given widely different interpretations. To avoid confusion, the following conventions are adopted for this chapter: (1) because OELs are the end result of a risk assessment process, risk assessors are responsible for setting an OEL, and (2) risk managers are responsible for recognizing, evaluating, and controlling exposures.

OCCUPATIONAL EXPOSURE LIMITS AND OCCUPATIONAL EPIDEMIOLOGY

Occupational exposure limits are the essential link between the process of risk assessment and the practice of risk management.[5] Although toxicology and animal studies are often reviewed and considered, for chronic disease agents it is often the exposure-response relationships from one or a handful of epidemiologic studies that form the basis for an OEL. In many cases the OEL represents a compact, distilled form of the relevant occupational epidemiology.

At its most basic, an OEL has three components: concentration, averaging time, and target.[6] For example, in 1987 the Occupational Safety and Health Administration[7] (OSHA) adopted a permissible exposure limit (PEL) for benzene of 1 ppm

and specified the averaging time as a single shift (8 hours).[8] The target of all legal and most authoritative OELs is the individual worker. For example, legal OELs, such as OSHA's PELs, and authoritative OELs, such as the recommended exposure limits (RELs) of the National Institute for Occupational Safety and Health (NIOSH) and the threshold limit values (TLVs) of the American Conference of Governmental Industrial Hygienists (ACGIH), are intended in principle to be applied to the exposures experienced by each employee. It is conceivable, however, that a company will devise a corporate OEL that has another target, such as an exposure group, work area, task, or occupation.

The level of protection afforded the individual worker will change if any of the components of an OEL are modified from those originally defined or intended by the risk assessor. For example, the level of protection is increased when a company sets and meets an internal OEL that is less than the legal limit. On the other hand, the level of protection is reduced if a company has a policy of comparing the average of multiple time-weighted average (TWA, the average concentration across a single work shift) measurements to a legal or authoritative OEL in which the averaging time was originally defined as a single shift. (Other means of reducing the nominal level of protection are discussed later.)

The process of setting or revising an OEL, especially at the federal level, can be cumbersome. As a result, OSHA's PELs are approaching 30 years of age. Considering that Congress may require extensive federal risk assessments,[9] we may soon reach the point of near stagnation in regard to new or revised federal OELs. Consequently, industrial hygienists have come to rely increasingly on OELs developed by authoritative bodies, such as the ACGIH, American Industrial Hygiene Association (AIHA), and NIOSH. For substances without OELs or newly created substances (e.g., pharmaceuticals), companies often develop internal or corporate OELs.[5,10,11]

For purposes of discussion we can divide risk assessors into governmental and nongovernmental agents. Governmental risk assessors are generally required to implement a comprehensive process of risk assessment.[12] A reading of OSHA's preamble to the 1987 benzene standard gives insight into the extensive process that now precedes the issuance of new or revised PELs. NIOSH's 1995 criteria document for respirable coal mine dust[13] is also worth reviewing, because it conforms closely to the current federal risk assessment model. The REL was based on consideration of epidemiology, sampling and analytic feasibility,[14] and technologic feasibility.

Nongovernmental risk assessors, such as the ACGIH and the AIHA, often utilize a less rigorous risk assessment process that gives diminished weight to technologic feasibility and lacks the mandate to protect "all" workers. Companies producing or using chemicals for which there are no federal or authoritative OELs often devise interim, company-specific OELs.[11]

RISK ASSESSMENT, RISK MANAGEMENT, AND RISK COMMUNICATION

Risk assessment, risk management, and risk communication are known as the triad of risk science. The definition of each may differ, depending on one's viewpoint. For example, the National Research Council[12] defined the concepts of risk assessment and risk management as they pertain to the agencies of the federal government charged with regulating environmental and occupational contaminants, drugs, and toxic substances in foods. Corporate or plant-level risk assessors and risk managers, academicians, and consultants may have slightly different definitions.

Risk Assessment

The National Research Council (NRC)[12] defined risk assessment at the federal level as "the qualitative or quantitative characterization of the potential health effects of particular substances on individuals or populations". Governmental risk assessment can be broken down into four steps,[12,15]: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization. According to the NRC, risk assessors assemble, analyze, and compare the health effects data. This information is then handed to the risk managers who are responsible for setting the air quality standard or occupational exposure limit after weighing the costs and examining feasibility issues. Others tend to view the recommendation of a reasonably "safe" level of exposure as the logical endpoint of the "risk assessment" process. Leung and Paustenbach[16] noted that

> A true risk assessment to *determine safe levels of occupational exposure* [emphasis added] actually requires exhaustive analysis of all the information obtained from studies of mutagenicity, acute toxicity, subchronic toxicity, chronic studies, pharmacokinetics, metabolism data, and epidemiology before a limit is recommended.

For Hallenbeck[17] the process of risk assessment involves identifying a potential hazard; characterizing its adverse effects in humans, animals, or cellular tests; determination of the relationship between dose or exposure and response; characterizing the exposures experienced by those employees in contact with the agent and the incidence or prevalence of disease; and, finally, the "recommendation of an acceptable concentration in air, food, or water." As stated before, this view is adopted in the present chapter.

Risk Management

The NRC[12] defined risk management as "the process of evaluating alternative regulatory options and selecting among them" and noted that a "risk assessment may be one of the bases of risk management." Risk management involves "value judgments" after considering the estimates of actual risk, the perceptions of risk in exposed populations and target industries, and the benefits and costs of control measures. In principle, a federal agency manages risk to the nation's workers in several ways: (1) by setting an OEL (concentration, averaging time, and target), (2) by requiring a minimal level of baseline monitoring and occasional resampling, (3) by requiring that exposures be adequately controlled, (4) by requiring a minimal level of medical monitoring, and (5) by occasionally auditing, through unannounced inspections, each company's ability to manage risk for its employees.

From the perspective of the plant manager or employer and the plant industrial hygienist, risk assessment is the process undertaken by the federal government or some authoritative organization to generate an OEL and related requirements. Risk management begins when the plant manager or employer hires the necessary staff or consultants and provides the resources for baseline evaluations, baseline exposure monitoring, periodic remonitoring, medical monitoring, and implementation and maintenance of controls, if necessary.

The first step in the process of risk management is the responsibility of the plant industrial hygienist: recognition that the hazardous substance is present in the plant. For the industrial hygienist the OEL is viewed as the output of a valid risk assessment process and functions as a practical tool for classifying work environments as either acceptable or unacceptable. The industrial hygienist accepts the concentration, averaging time, and target as specified, either explicitly or implicitly, by the OEL and seeks to maintain exposures at levels less than the OEL. The industrial hygienist utilizes the resources made available by upper management and determines whether

the risk of disease is properly and effectively managed for each employee under the industrial hygienist's care. For the industrial hygienist, risk management— or, as some call it, occupational exposure management—consists simply of the traditional industrial hygiene triad of recognition, evaluation, and control. It can be safely said that the industrial hygienist is the ultimate occupational exposure (risk) manager.[18]

Risk Communication

At the federal level risk communication takes the form of OSHA and MSHA exposure standards and regulations, NIOSH-recommended exposure limits and publications, and the various OSHA, MSHA, and NIOSH training and educational programs. Risk communication to individual workers primarily falls to the industrial hygienist.[19]

CONSIDERATIONS WHEN SETTING OELS

In interpreting the occupational epidemiology and establishing an OEL, the risk assessor must address several issues. Three are considered here:

- Extrapolating from cohort to individual worker
- Selecting a level of "significant risk"
- Controlling lifetime risk with measurements of single-shift exposures

Extrapolating from Cohort to Individual Worker

In studies in which historical exposure data are available, the occupational epidemiologist constructs job-exposure matrices to determine the cumulative or average exposure of each member of the cohort for the period of the study. Consequently, the exposure experience of an exposure group is assigned to each worker in that group for each observation period, commonly each month or year of the study. Because individual workers move from group to group for differing amounts of time, the range of cumulative or average exposures may vary substantially, resulting in unique pairs of response measurements and cumulative or average exposures. The exposure-response analysis focuses on estimating the expected average response corresponding to specific levels of cumulative or average exposure. It is often possible, even desirable, to determine the cumulative or average exposure corresponding to a level of "significant risk." However, the level of response or risk at any average or cumulative exposure is an average level for a hypothetical group. Some individuals within the hypothetical group will experience a higher risk and others a lower risk.[20,21] The range of these differences reflects lack of knowledge about such factors as individual sensitivity and the fact that the estimates of exposure are usually crude and group-based and do not capture true individual exposure differences.

How then does one translate an acceptable average or cumulative exposure for a hypothetical exposed group to an individual worker? This question is relevant for two reasons:

1. Federal laws (and common sense) mandate that each worker or miner has a right to expect, to the extent possible, "safe and healthful working conditions" throughout his or her working life.[22,23] Thus risk managers at the corporate and plant level must control exposures and manage the risk of disease for each employee. It is not sufficient that the exposures are, on average, acceptable within an exposure group or across a plant or industry, because some individuals within the group will experience, on average, greater exposures.[20] In summary, the risk of disease should be properly managed for each employee.

2. Companies are increasingly aware that both OELs—federal, authoritative, or corporate—and effective risk management are necessary to minimize both employee

injury claims and "product liability suits" on the part of users of chemical products.[11] Again, it is necessary to set an OEL that is considered protective for each exposed individual and not just for some larger exposed population.

Selecting a Level of Significant Risk

The concept of "significant risk" has received a great deal of attention in regard to carcinogenic agents. OSHA now uses guidance provided by the U.S. Supreme Court and considers a risk of 1-in-1000, for a working lifetime, as significant (i.e., unacceptable) and necessitating some sort of regulatory action.[24] OSHA recently requested guidance in defining significant risk for noncarcinogenic disease endpoints.[25] NIOSH[13] referred to the significant risk concept of 1-in-1000 when recommending an exposure limit for respirable coal mine dust, a noncarcinogen that can produce irreversible disease.

The ACGIH has no stated policy regarding significant risk. TLVs are set at values that are "believed" to be protective of "nearly all workers." Many TLVs are based on concentrations with "no observed effect,"as reported in the literature, or levels at which the risk does not significantly exceed the risk in unexposed workers. Few, if any, TLVs are based on a rigorous risk assessment process with the goal of reducing risk to the 1-in-1000 guideline established during the OSHA benzene deliberations.[26] (This is not to say that TLVs are invalid, because they are often modified to reflect current health effects in the literature and may result in recommended control values more stringent that those of OSHA or NIOSH.)

Controlling Lifetime Risk with Single-Shift TWA Measurements

For purposes of risk assessment, it is desirable to estimate long-term cumulative or average exposures.[27] For purposes of risk management, it is usually not feasible to estimate the long-term average exposure of each employee.[28] The general practice is to set a single-shift OEL equal to the long-term average exposure that appears to be acceptable or suitably protective, based on exposure-response analyses. This practice recognizes (1) the need to devise OELs that can be used for purposes of day-to-day risk management, (2) the need to control the long-term, working-lifetime exposure of each individual worker to protective levels, and (3) the philosophical requirement that each OEL embody a safety factor.

Consequently, in a "controlled" work environment exposures rarely or infrequently exceed the OEL. The expectation is that by limiting the fraction of exposures exceeding an OEL, the true long-term mean exposure is indirectly controlled to an acceptable level for each individual. During its deliberations over revision of the benzene PEL, OSHA considered proposals for defining the PEL as either a 5-shift, 40-hour average or a long-term mean, calculated from n measurements collected over some defined period.[7] OSHA rejected these proposals as difficult to implement both by OSHA, when conducting inspections, and by most employers. Furthermore, OSHA observed that a long-term average exposure at the benzene PEL still contained significant residual risk. OSHA reasoned that only by defining the PEL as a limit for each single-shift TWA will individual workers be adequately protected. The NIOSH RELs are based on this philosophy, and it appears that the ACGIH TWA TLVs are also consistent with it.

In summary, occupational epidemiologists and risk assessors may think in terms of long-term, working-lifetime exposures when extracting protective exposure levels from exposure-response relationships; however, in suggesting acceptable levels of exposure for day-to-day risk management by industrial hygienists, the OEL

should reflect the fact that exposures for chronic disease agents are measured across one shift at a time, and, given typical practices in industry, few measurements are available for any particular worker.

USING OCCUPATIONAL EXPOSURE LIMITS TO CONTROL EXPOSURES: CURRENT PRACTICE

A risk assessment of some sort is necessary to produce an OEL for a chronic disease agent. However, once an OEL is established, concern shifts from risk assessment to risk management. Risk management (also called occupational exposure management) has long been recognized as basically a problem of "quality control" or "statistical process control."[21,29–33] In terms of statistical process control, the OEL is an "upper specification limit" or "upper control limit." Consequently, the objective of an effective exposure monitoring program is periodically to obtain sufficient, valid, and representative exposure measurements so that the work environment for each individual worker is accurately classified as either acceptable or unacceptable for each "observation period."[34] Also, the objective of an effective exposure control program is to ensure that most, if not all, of the exposure measurements are less than the TWA OEL.[7,21,30,31,36,40] Exposure monitoring is a long-term responsibility that does not end until the substance in question is no longer used.[36] Processes change, controls deteriorate, and new workers are introduced. thus there is always a need for resampling and internal audits.[31]

Exposures need not be controlled to the extent that absolutely no random exposure ever exceeds a TWA TLV or TWA PEL. Even in a well-controlled work environment an occasional outlier may occur (interpretation of a single over-exposure is discussed later). Consequently, the practical goal of each employer or risk manager is to provide each employee a "controlled" work environment; that is, an environment in which exposures rarely or infrequently exceed the OEL. Such a goal does not lose sight of the fact that risk for chronic disease agents is usually best characterized by the average or mean exposure. By limiting single-shift excursions above the TWA OEL, the true long-term mean exposure for each employee is indirectly maintained at a level well below the TWA OEL.[7,35,36]

The primary goal of any exposure assessment strategy should be to determine whether the work environment is acceptable for each exposed worker. A common secondary goal is to determine whether the work environment is in compliance with the minimal requirements of a federal or state OEL.[37] Three basic approaches have evolved for determining the acceptability of a work environment:

- Individual-based exposure assessment strategies[38]
- Maximum risk employee-based exposure assessment strategies
- Group-based exposure assessment strategies

Individual-Based Exposure Assessment Strategy

Ideally, the exposures experienced by each employee should be regularly estimated, preferably by several exposure measurements collected either in campaign fashion (i.e., within a short period or during consecutive shifts) or across several months. The industrial hygienist then estimates various exposure parameters; for example, arithmetic and geometric means, 95th percentile exposure (and upper confidence limit for the 95th percentile, also called the upper tolerance limit), and the fraction of exposures expected to exceed the OEL. If the 95th percentile is less than the OEL, one can state that apparently the distribution of exposures is suitably controlled for the individual employee. If the 95% upper tolerance limit is less than the

OEL one can state, with 95% confidence, that exposures are controlled. However, regular monitoring of all exposed employees is, for practical reasons, not often implemented. For some occupations or work environments, in which there are only a few workers and exposures range from significant[39] to poorly controlled, periodic montioing of 100% of workers is entirely feasible and necessary.

Maximum Risk Employee-Based Exposure Assessment Strategies

Early in the 1970s NIOSH and OSHA recognized the need for sampling strategies and decision logics that would impose a "minimum burden to the employer (i.e., risk manager) while providing adequate protection to the exposed employees."[40] NIOSH devised an exposure assessment strategy designed around (1) selection of the "maximum risk employee" (MRE) or the "employee (per exposure group) presumed to have the highest exposure risk," and (2) collection of one or a few exposure measurements. NIOSH reasoned that if the exposures of the MRE are judged acceptable, based on the NIOSH logic,[41] then each individual worker in the exposure group represented by the MRE is adequately protected. Consequently, although the focus may be on one or more MREs per exposure group, the goal is to ensure that the exposures for each worker are adequately controlled.

The weaknesses of this strategy have been recognized.[40,42–44] The primary problem is that the strategy has poor power in regard to detecting truly unacceptable work environments.[42] However, even if NIOSH had recommended a statistically sound, rigorously designed strategy, it would have been roundly criticized as impractical for businesses of limited means. OSHA incorporated versions of this strategy in numerous 6(b) standards[45] but recognized that such a strategy represents a token commitment that does not accurately classify all work environments.[46] The ability of industrial hygienists to select reliably one or more MREs from an exposure group has also been questioned by several researchers. Nonetheless, for initial evaluations or when resources are limited or resampling intervals are broad, the MRE concept is both recommended and commonly used by industrial hygienists as a means of efficiently determining the acceptability of the work environment for members of an exposure group.[40,47–49,71,85]

Group-Based Exposure Assessment Strategies

Corn and Esmen[50] described an exposure assessment strategy based on the concept of an exposure group or, as they called it, an "exposure zone." Basically, workers are aggregated on the basis of work similarity, exposure agent(s), environment similarity, and identifiability. A single exposure measurement is collected from each of *n* randomly selected workers per exposure group and a standardized exposure parameter *phi* is calculated. The *phi* value (basically a Z-value) permits one to estimate the fraction or number of employees expected to have exposures in excess of the OEL.[50,51] If the expected number is one or greater, "a hygienic problem exists"[50] and should be addressed. This strategy was designed so that a decision is reached for each exposure group with a limited number of measurements. The measurements obtained from the group are believed to characterize the work performed by each group member and therefore can be extrapolated to all members of the exposure group, measured or not.

Similar strategies have been described by others.[31,36,52,53] Roach[31] described a "health risk surveillance" strategy in which the exposures for a reasonably homogeneous "job-exposure group" are acceptable if they are "consistently below one-third the exposure limit." Still and Wells[52] acknowledged the efficiencies of the "screening" sample approach (basically the MRE-based strategy discussed above) but

leaned toward collecting sufficient measurements to estimate the 95th percentile exposure and its 95% upper confidence limit (the 95% upper tolerance limit), which would be compared with the TWA OEL. The AIHA Exposure Assessment Strategies Committee[36] added the concept of the "homogeneous exposure group" (HEG). An HEG is an exposure group in which the workers have "identical probabilities of exposure to a single environmental agent," although on any single day the exposures will vary. For an initial or baseline evaluation, the industrial hygienist should randomly select 6–10 workers per HEG and collect 6–10 measurements over a relatively short period. The industrial hygienist then analyzes the data and decides, using a combination of "statistical analysis and professional judgment," whether the "exposures demonstrate an acceptable work environment."[54] Exposures for an HEG are usually deemed acceptable if it is highly likely that 90 or 95% of the measurements are less than the OEL (determined by using upper tolerance limits). After the baseline data are collected, the adequacy of the "HEG assumption" can be determined by qualitatively examining the linearity of the log-probability plot of the exposure data. However, such a procedure primarily addresses the assumption that the data are lognormally distributed. The committee provided no criteria or objective procedures for determining whether a particular combination of workers and "process/agent/task" results in reasonably homogeneous exposures.

The European standard for exposure assessment adopted by the Comité Européen de Normalisation (CEN)[55] is also based on the HEG concept. CEN acknowledges that within an HEG exposures are subject to both "random and systematic" variation and provides a "rule of thumb" for assessing group homogeneity.[56] This standard contains simple decision rules for classifying each exposure measurement collected from an HEG. However, if six or more measurements are randomly collected, one can use statistics to estimate the probability of overexposure for individuals within the HEG. CEN suggests that if this probability is less than 0.1% and the work environment is reasonably stable, exposure monitoring can be reduced or eliminated until a significant change occurs. If this probability exceeds 5%, corrective action should take place. Otherwise, periodic monitoring should be used to confirm that the point estimate of the probability of overexposure remains less than 5%.

These strategies are obviously best suited to exposure groups that are reasonably homogeneous; that is, systematic differences among the individual exposure distributions of the group members are minor. If the exposure group is heterogeneous, with large systematic differences among individuals, such a strategy may miss group members who are routinely overexposed.[55] With the usual number of measurements collected per exposure group, one often has to accept on faith that the exposure groups are reasonably homogenous. Several researchers have shown that exposure groups often have a great deal of between-worker variability.[57,58] Consequently, this assumption may not be valid without an analysis of objective data.[59]

The overall goal remains the assessment of exposures for the individual worker, albeit in an indirect fashion. For the sake of efficiency,[60] it is assumed that exposures collected from the exposure group and inferences from the analysis of said exposures can be applied to any and all members of the exposure group.[36,48,50,52] This assumption is valid to the extent that the exposure group is reasonably homogeneous.

MODELS OF COMPLIANCE FOR CHRONIC DISEASE AGENTS

What does it mean to be "in compliance" with a TWA OEL? This question can be addressed by looking first at the distribution of shift average exposures (i.e., the

distribution of TWAs) and next at the distribution of short-term exposures within a single shift.

Between-Shift Control Models

Figure 1 illustrates the between-shift variation expected in a minimally controlled work environment for an individual worker. Overexposures are infrequent, and the long-term mean is a fraction of the TWA OEL. There are basically two between-shift control models: the indirect and the direct. The commonly applied indirect control model holds that the distribution of exposures for an individual worker is controlled when overexposures occur infrequently. Several authors and authoritative sources recommend that the exceedance fraction (fraction of measurements above the OEL) should be no more than 0.05.[21,36,40,48,52,55,61] For example, NIOSH[40] stated the following goal for an effective exposure assessment program: "In statistical terms, the employer should try to attain 95% confidence that no more than 5% of employee days are over the standard."

Along similar lines OSHA[46] indicated that a well-designed exposure sampling strategy that results in "95% certainty" that employees are exposed below the PEL provides "compelling evidence that the exposure limits are being achieved." Although not stated with the rigor that a statistician would desire, OSHA's intent is clear: compelling evidence that compliance is routinely achieved can be developed by a statistical analysis of exposure measurements. For example, the often used one-sided upper tolerance limit test, in which one is 95% confident that 95% of the measurements are less than the OEL, is consistent with the NIOSH statement and may be considered "compelling evidence," as mentioned by OSHA.

Figure 2 shows several exposure distributions that may be considered minimally 'acceptable" according to the indirect control model. The range of GSDs (1.5–3.0) covers the range of most within-worker GSDs commonly observed in practice.

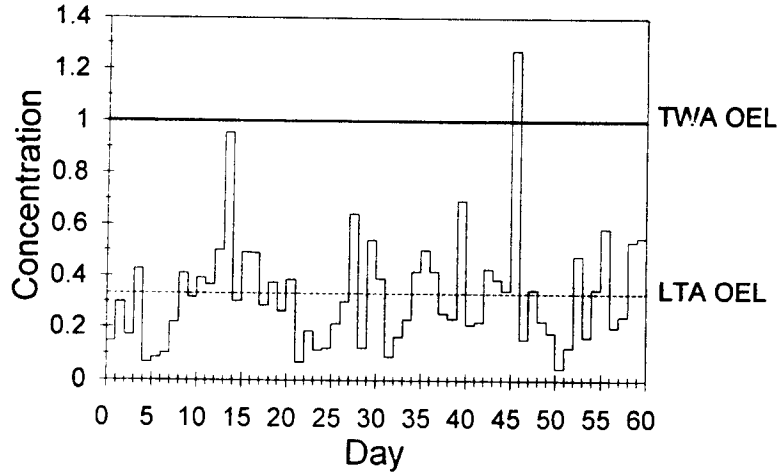

FIGURE 1. Simulated time series of 8-hour TWA exposures depicting a "controlled" work environment. Single shift excursions above the TWA OEL are "infrequent" and the long-term mean is approximately ⅓ (TWA OEL).

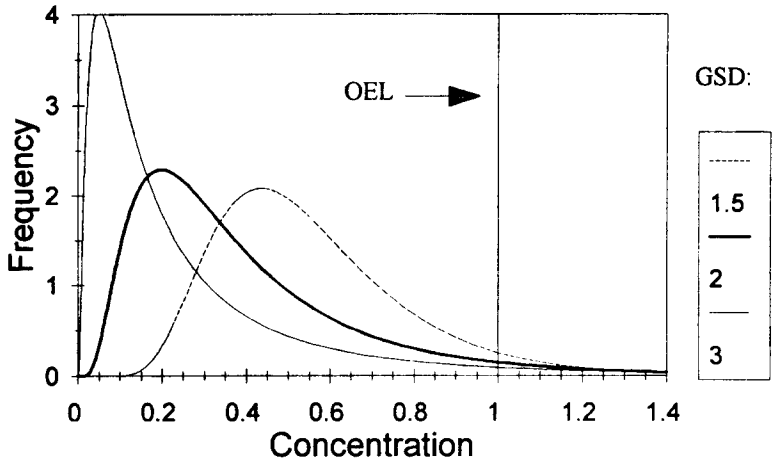

FIGURE 2. "Indirect control" model. Hypothetical single shift limit, or OEL, is set at 1. The exceedance fraction is fixed at 0.05 for each distribution.

GSD	Mean	% > OEL	% > OEL'	% > 1.5 • OEL	% > 2 • OEL
1.5	0.56	5%	2.3%	0.4%	< 0.1%
2.0	0.41	5%	3.2%	1.3%	0.4%
3.0	0.30	5%	3.8%	2.2%	1.1%

(The effective OEL, or OEL', is the critical value for issuing a citation (assuming $CV_T = 0.1$): OEL' = OEL • (1 + 1.645 • CV_T) = 1.16 = 1(1 + 1.645 • CV_T) = 1.16.)

The direct control model requires that the distribution of exposures for a worker be controlled to the point that the distribution mean is some fraction of the TWA OEL. For example, the AIHA[36] suggests that a "typical LTA (i.e., long-term average exposure limit) may be one-third of an 8-hr PEL."[62,63] Roach and Rappaport[64] suggest that exposures be controlled so that the long-term average exposure is one-tenth or one-fourth of the applicable ACGIH TLV, thus limiting the fraction of overexposures to 0.01–0.05. Figure 3 shows several exposure distributions that may be considered minimally acceptable according to the direct control model. The mean of each distribution is controlled to an LTA OEL set at $^1/_3$ • OEL, as suggested by the AIHA. The exceedance fraction varies from 0.002–0.061, depending on the underlying distribution.

Both models have limitations. The indirect control model has two chief limitations: (1) the long-term mean exposure is controlled to different levels, depending on the underlying GSD, and (2) the long-term mean exposures for distributions with GSDs less than 1.5 will exceed half of the TWA OEL and even approach the OEL for extremely low GSDs. Because this control model is commonly used, this limitation points to the need for risk assessors to indicate clearly the long-term goal of a single-shift TWA OEL for a chronic disease agent. For example, routine compliance with a single-shift TWA OEL should result in a long-term, multiyear average exposure of each exposed employee that is no more than a specific fraction of the single-shift OEL, regardless of the underlying variability of exposures. The direct control method has several limitations: (1) single-shift exposures are occasionally expected to exceed greatly the TWA OEL for exposure distributions having GSDs greater than roughly three; (2) low variability distributions may be perceived as "overcontrolled;" and (3),

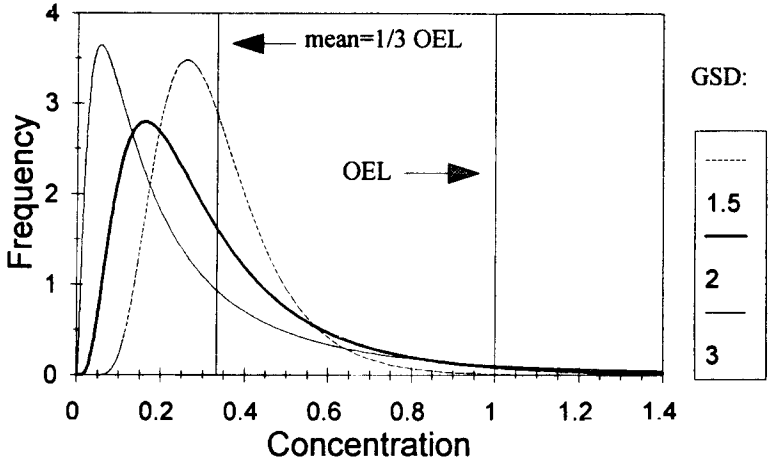

FIGURE 3. "Direct control" model. Hypothetical single shift limit, or OEL, is set at 1. The long term OEL is fixed at ⅓ the single shift OEL, per the recommendation of the AIHA.[36]

GSD	Mean	% > OEL	% > OEL'	% > 1.5 • OEL	% > 2 • OEL
1.5	0.333	0.2%	< 0.1%	< 0.1%	< 0.1%
2.0	0.333	2.7%	1.6%	0.6%	0.2%
3.0	0.333	6.1%	4.6%	2.7%	1.5%

(The effective OEL, or OEL', is the critical value for issuing a citation (assuming $CV_T = 0.1$): OEL' = $1(1 + 1.645 \cdot CV_T) = 1.16$.)

in general, more measurements and time are necessary to determine whether exposures are controlled in relation to a long-term mean standard.

In reality, which model is adopted for an existing TWA OEL is largely academic. Convincing many employers to practice effective risk management by any model appears to be the major problem facing regulatory agencies. For the range of GSDs considered, either model, if effectively applied, will control an individual worker's long-term average exposure, i.e., the average TWA, to roughly half or less of the TWA OEL and limits single shift excursions above the OEL to a low percentage.[35] Either model also reduces the probability of a citation to less than 5% for an individual worker. For example, the legends of Figures 2 and 3 contain estimates of the fraction of exposures above the effective OEL, or the citation value.[65] These estimates range from less than 0.1% to 4.6% for the underlying GSDs considered. In summary, a minimally controlled distribution of exposures, using either model, controls to arguably acceptable values the long-term mean, single-shift excursions above the OEL and the probability of a citation.

A third compliance model, advanced in recent years, is mentioned only for the sake of completeness. This model focuses on characterizing the distribution of individual long-term mean exposures within an exposure group.[66,67] Implementation, as envisioned by Rappaport et al.,[67] requires repeat measurements from 10 or so workers per exposure group and uses a complex analysis procedure. Basically, the goal of this model is to control the probability that any single worker's long-term mean exceeds a LTA OEL to a low value (e.g., 0.10, as recommended by Rappaport et al.[67]) In principle, it is incorrect to apply this model to a TWA OEL; it is designed for determining compliance with an LTA OEL.

Within-Shift Control Model

The ACGIH recommends excursion limits for controlling within-shift exposures. The excursion limits and the supporting documentation readily permit the construction of a control model for the within-shift distribution of exposures. Basically, the ACGIH believes that within-shift excursions can be controlled in the majority of work environments so that short-term exposures, typically measured over 15-minute intervals, infrequently exceed three times the TWA TLV and rarely, if ever, exceed five times the TWA TLV. Figure 4 illustrates a minimally controlled distribution of within-shift exposures according to ACGIH recommendations. The ACGIH does not require routine assessment and control of TWA exposures with short-term measurements. The excursion limits appear to be directed at describing good practices and preventing abuse of the TWA TLV concept (discussed later). OSHA adopted a similar approach in the recently revised asbestos standard[68]: "Excursion limit. The employer shall ensure that no employee is exposed to an airborne concentration of asbestos in excess of [10 times the PEL] as averaged over a sampling period of thirty (30) minutes."

Interpretation of One or More Overexposures

The above models of compliance are useful for constructing a mental concept of what the distribution of exposures should look like for each employee. Sufficient exposure measurements for estimating, either by log-probability plotting or through a histogram, the distribution of exposures for any single exposure group are often unavailable, let alone sufficient measurements for characterizing the distribution of exposures for any single employee.[69] Figure 5 depicts a time series of 36 consecutive TWA measurements for a worker exposed to inorganic lead.[70] These measurements were collected as part of a research project. The single overexposure, when compared with the 1995–1996 ACGIH TLV for inorganic lead, is not likely to be a cause for great concern when considered in context with the other 35 measurements (the average measurement was 37% of the TLV). However, if only the measurement

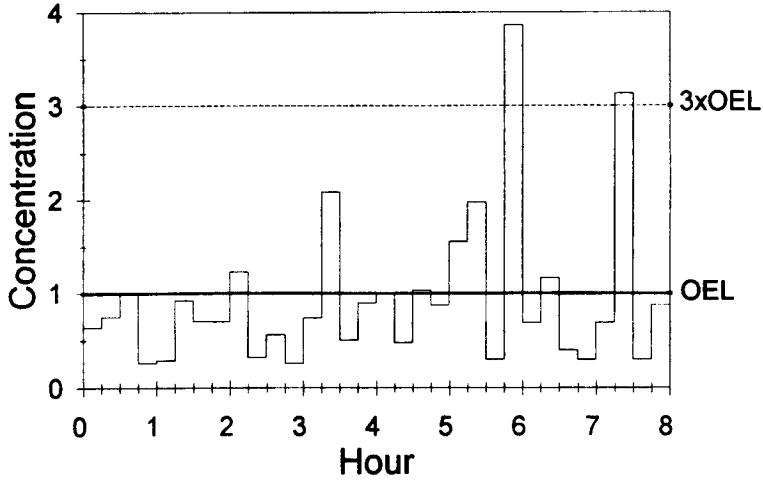

FIGURE 4. Simulated 15-minute short-term (average) exposures across a single 8-hour workshift where the within-shift exposures are minimally controlled (short-term excursions above 3 • OEL are infrequent and the TWA OEL is not exceeded).

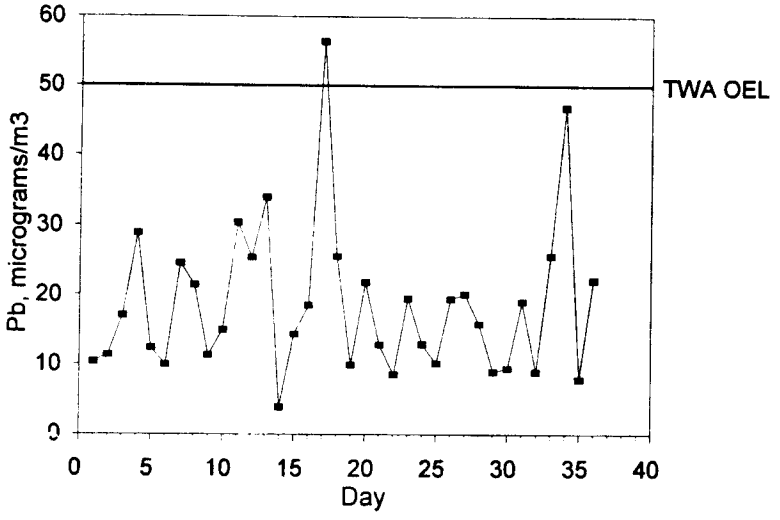

FIGURE 5. Consecutive measurements of airborne inorganic lead for "Worker A" of Cope et al.[47]

on day 17 were available, how would one or more overexposures be interpreted for purposes of effective risk management?

Authoritative sources recommend investigation of each overexposure.[31,40,47–49,52,55,71] The exceedance fraction calculations in the legends for Figures 2 and 3 suggest that in controlled work environments random exposures above the TWA OEL and, for example, 1.5 or 2 times the TWA OEL are infrequent to rare. Therefore, any over-exposure in which the number of measurements is small should be a cause for concern. Also, the work of Nicas et al.[72] suggests that overexposures should not be blamed on measurement error. Simply put, each overexposure should be investigated.[73] If compelling or convincing past exposure data[74] suggest that the overexposure is most likely an anomaly, it is reasonable to take no action beyond merely documenting the investigation. However, if no rational explanation can be found for the overexposures, one is compelled to conclude that a systematic change of some sort may have occurred; after all, in a controlled work environment overexposures should be rare to infrequent (for example, see Figs. 2 and 3). Follow-up actions may consist of fine tuning existing controls, installation or modification of controls, or evaluation of individual work practices. In any case, additional measurements are usually warranted to verify the need for additional controls or to evaluate the effectiveness of any intervention.

Criticisms and Defense of Occupational Exposure Levels

The ACGIH TLVs have been criticized for not being based on a rigorous risk assessment process and for being subject to industry influence.[26,64,75,76] The ACGIH[20,77] defended its policies, arguing that much of the criticism was either unwarranted or unsupported and that, in the absence of better documented or more rigorously developed standards, TLVs have long served to assist occupational health professionals in assessment and control of exposures.

Although many TLVs have since been revised downward and hundreds more added, OSHA continues to enforce the 1968 TLVs as permissible exposure limits (PELs). Despite the fact that the PELs are out of date and badly in need of revision,

several researchers[43,44,78,79] have argued that in adopting the 1968 ACGIH TLVs, OSHA improperly defined the PELs for chronic disease agents as control limits on the average exposure across each shift rather than limits on the working-lifetime average exposure. However, such views appear to be in the minority. Stokinger,[80–84] Roach et al.,[85] and the many other authorities discussing the ACGIH TLVs provide abundant evidence that TWA TLVs, and by extension TWA PELs, were and are intended to be interpreted, for purposes of risk management, as upper limits for each TWA exposure.[86] Practicing industrial hygienists routinely interpret ACGIH TLVs and OSHA PELs as upper limits for the average exposure of each employee across each shift.[36,40,48,49,50,52] Furthermore, in the preface of the 1968 TLV booklet the ACGIH[87] clearly stated:

> (1) Time-weighted averages permit excursions above the limit provided they are compensated by equivalent excursions below the limit *during the workday* [emphasis added].[88]
>
> (2) Enlightened industrial hygiene practice inclines toward controlling exposures to below the limit rather than maintenance at the limit.

Nonetheless, the notion that OSHA "got it wrong" continues to be discussed.

Misinterpretation and Misuse of the Concept of Occupational Exposure Levels

There are numerous ways in which the OEL concept can be misinterpreted or misused:

- Interpreting OELs as "fine lines between safe and dangerous"
- Using an 8-hour TWA OEL to assess short-term exposures
- Using 8-hour TWA OELs to devise community air quality standards
- Applying 8-hour TWA OELs to "novel" work schedules
- Comparing an exposure group's average exposure to a TWA OEL
- Extending the averaging time from a single shift to multiple shifts
- Interpreting the TWA OEL as a long-term average (LTA) OEL

Stokinger[80,84,89] mentioned several ways in which the ACGIH TLVs were misinterpreted and misused. First, some interpreted the TLVs as "fine lines between safe and dangerous concentrations."[90] One or a few TWA measurements that are just under the TLV do not imply that exposures are adequately controlled during the remaining unmeasured shifts. Second, some were using 8-hour TWAs to assess short-term exposures. The TWA TLVs are not appropriate for high-exposure tasks that last only a fraction of the shift. For example, if a task lasts only 30 minutes, it is not permissible to permit up to16 times the TWA TLV, even if the daily average is less than or equal to the TWA TLV. Beginning in the early 1970s, the TLV committee felt compelled to recommend specific within-shift excursion limits to prevent this type of abuse. For example: "Excursions in worker exposure levels may exceed 3 times the TLV-TWA for no more than a total of 30 minutes during a workday, and under no circumstances should they exceed 5 times the TLV-TWA, provided that the TLV-TWA is not exceeded."[91] Finally, TLVs were occasionally applied to community or environmental exposures. The TLVs were designed for healthy, working populations and should not be used for "limiting pollutants in urban community air" where exposures are 24 hours per day and susceptible subpopulations are affected.[92]

Brief and Scala[93] noted that the TLVs were designed for a traditional 8-hour work shift and 40-hour workweek. They proposed a conservative method for reducing the TLVs to reflect a "novel" work schedule. Extended workshifts and/or more than 40-hours of exposure per week reduce the recovery time for each worker and

"stretch the reliability and even viability of the data base for the TLV."[94] The ACGIH[91] recommends that, among other models, the Brief and Scala model be used as guidance for reducing the TLV during a nontraditional work schedule. OSHA adopted a simpler scheme for the 1978 lead and the 1994 cadmium PELs.

Occasionally industrial hygienists compare the average exposure of an exposure group to a TWA OEL. This practice changs the OEL's target from the individual worker to the exposure group and is valid to the extent that the exposure group is homogeneous. For a group in which there are systematic and significant differences between worker exposures, a practice of routinely comparing the group average exposure to an OEL may permit some workers to be routinely overexposed.[21] Such a practice was considered and rejected by NIOSH[40] as a valid technique for determining compliance with legal OELs except under the extraordinary circumstance when the overall GSD for the exposure group is 1.15 or less (meaning that, for practical purposes, the exposure group is truly homogeneous).[95]

An OEL can be weakened by extending the averaging time for a single measurement from a single shift to multiple shifts.[49] For example, a practice of comparing the average of n TWAs to an OEL in effect creates an OEL′ defined as the average of n TWA measurements, which is contrary to the intended interpretation of the OSHA TWA PELs, NIOSH TWA RELs, and ACGIH TWA TLVs. Such a practice explicitly permits frequent single-shift overexposures and creates an OEL′ that does not provide the level of protection inherent in the original OEL. When issuing the 1978 final lead PEL, OSHA explicitly forbade multishift averaging:

> The proposed standard expressed the PEL as an 8-hour, time-weighted average "based on a 40-hour week." This [language] has been deleted [from the final standard] to avoid ambiguity since it was misconstrued by some commenters as a conversion of the PEL to a 40-hour average.[96]

The ACGIH[91,94] expressly forbids redefining the TLVs: "it is not appropriate for individuals or organizations to impose on the TLVs . . . their concepts of what the TLVs . . . should be or how they should be applied." Although it is abundantly clear to most practicing industrial hygienists that the TWA TLVs are defined as limits for each TWA exposure, a minority insist that the TWA TLVs represent long-term, even lifetime average exposures. Such a view basically redefines the TWA TLVs, extending the averaging time from a single shift to months or years or even the employee's working lifetime. Because the long-term average exposures permitted by this practice can be double or more over those that result when the TLV is properly interpreted as an upper control limit for each TWA, the level of protection provided by such a modified TLV cannot possibly equal the level of protection provided by the original TLV. Because OSHA's TWA PELs and NIOSH's TWA RELs are clearly defined as upper limits for each single-shift average exposure (TWA), it is clearly inappropriate to manage exposures as if they represented limits on long-term, average exposures.

SOURCES OF OCCUPATIONAL EXPOSURE LEVELS

The number of chemicals found in the nation's workplaces is literally in the tens of thousands.[11] However, OELs have been established for only 2000 or so substances. In general, plant industrial hygienists look to OSHA and MSHA for legal OELs and to the ACGIH, AIHA, and NIOSH for authoritative OELs. In the absence of a legal or authoritative OEL, many corporations devise internal or corporate OELs.[11]

American Conference of Governmental Industrial Hygienists

The history of the ACGIH and TLVs has been well described elsewhere.[80,97] The ACGIH TLV list now contains over 700 recommended exposure limits for substances ranging from simple irritants to chronic disease agents and carcinogens. The ACGIH TLV committee consists primarily of professionals recruited from the ranks of government (federal and state) and academia. It is well known that for decades the TLVs represented the only available exposure guidelines and before the creation of OSHA, MSHA, and NIOSH served well the occupational health community. Given the lengthy process required to update each OSHA PEL, the current TLVs are considered by many to represent the best available information on acceptable exposures for the majority of the listed substances.

The ACGIH TLVs for airborne substances are defined as upper limits for the average concentration across the indicated averaging time. For substances with acute or short-term effects, the ACGIH recommends a short-term exposure limit (STEL).[98] The averaging time for this limit is 15 minutes. For slower-acting substances or substances that produce a chronic effect, the ACGIH recommends a TWA TLV. The averaging time for this limit is a single shift (8 hours). The ACGIH recommends that TWA TLVs be reduced when workshifts are longer than 8 hours and/or the work week consists of more than 40 hours.

ACGIH[91] introduces the TLVs with what is basically a risk assessment statement: "[TLVs] refer to airborne concentrations of substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse effects." The ACGIH TLV committee believes that routine exposures at the level of the TLV will be protective but allows that a small percentage of workers may develop occupational illness. Consequently, one can be reasonably confident that this statement will hold true for an individual worker by ensuring that exposures are routinely maintained beneath the TLV. Thus, for risk management purposes, the ACGIH[91] defines the TWA TLVs as limits for the average exposure across each 8-hour shift. Stokinger[84] recommends that users consult the documentation for each TLV to determine the basis for the TLV and the "safety factor," if any, inherent in each TLV. For example, the 1971 documentation for the crystalline silica TWA TLV leaves no doubt about the TLV committee's intentions[99]: "The margin of safety of the quartz TLVs is not known. In the documented examples of virtual silicosis elimination, concentrations have averaged well below the TLV. It is suggested that quartz concentrations be maintained as far below the TLV as current practices will permit."

A nearly identical caution is given in the 1991 documentation.[94] The 1971 documentation for coal dust reveals that the TWA TLV was based on the interim results of a long-term study of British coal workers. The authors of the study estimated that 35 years of exposure at 2.2 mg/m^3 was correlated with a near zero probability of category 2 pneumoconiosis. The 1991 documentation[94] for benzene accepted a conclusion of the authors of a mortality study that 0.1 ppm as a working lifetime average would reduce the odds of "benzene-induced leukemic death" to near the odds for unexposed populations. These are examples of risk assessments looking at group average exposures and group average responses. For risk management purposes, the recommended TWA TLVs for silica, coal dust, and benzene are defined by the ACGIH as upper limits for single shift exposures in order to (1) adequately protect individual workers and (2) partially account for the uncertainty in the epidemiologic data. A review of the ACGIH 1991 documentation for OSHA's 6(b) substances, most of which are considered chronic disease agents, reveals that the ACGIH also advocates

the use of within-shift excursion factors for nearly all of these substances[100] and in many cases states explicitly that TWA TLV is nearly equivalent to the corresponding OSHA PEL and NIOSH REL (which are defined as limits for single-shift exposures).

The ACGIH TLV committee for chronic disease agents and carcinogens has several advantages over OSHA and NIOSH. For instance, the TLV committee can rapidly recommend new or revised TLVs in response to advances in the epidemiologic or toxicologic literature. The TLV committee is not required to examine closely issues of feasibility for all affected industries or to engage in lengthy cost-benefit debates. This happy state of affairs may be changing, because the ACGIH sometimes finds itself threatened with lawsuits upon recommending a reduction in a TLV, forcing the ACGIH to increase the level of documentation and to engage in lengthier risk assessment deliberations. Another advantage is that the ACGIH TLV committee is not required to recommend a TLV that protects the overwhelming majority of workers, but only one that is believed to be protective for "nearly all" workers.[91] Consequently, the ACGIH does not get mired in disputes with industry regarding definitions of significant risk. Others view this as a disadvantage, arguing that the TLVs do not provide adequate protection for enough workers[64] or for susceptible subgroups.[101] In summary, specific ACGIH TLVs may not be as protective as the more recent OELs of OSHA and NIOSH; taken as a whole, however, the TLVs reflect more accurately current changes in the understanding of the relationship between exposure and occupational disease.

American Industrial Hygiene Association

The AIHA issues guidelines for workplace environmental exposure levels (WEELs) for substances for which there are no authoritative or legal OELs.[102,103] The number of WEELs on the current list is less than 100. Candidate substances are solicited from the AIHA membership or suggested to the WEEL committee. Unlike the ACGIH, members of the AIHA WEEL committee can be currently employed by industry, but the procedures used by the WEEL committee are similar to those used by the ACGIH TLV committee. Like the TLV committee, the WEEL committee believes that each WEEL will "provide a level to which nearly all workers may be repeatedly exposed, for a working lifetime, without adverse health effects."[103] Also like the TLV committee, for risk management purposes the AIHA defines the WEELs as upper limits for each 8-hour work shift (assuming the typical 40-hour work week) or as ceiling values not to be exceeded during each shift.

Occupational Safety and Health Administration

OSHA[22] is permitted to "promulgate" occupational health standards that ensure "most adequately . . . to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life."

OSHA initially adopted existing consensus air quality standards and standards already in effect under the Walsh-Healy Public Contracts Act. These consisted of the 1968 ACGIH TLVs and various ANSI Z committee standards, which resulted in an initial list of PELs that numbered slightly more than 400. OSHA soon found that the promulgation process was cumbersome and slow because of the frequent demands for scientific certainty placed on government risk assessors and the fact that accurate exposure-response relationships are often difficult to obtain with the available exposure data, reflecting the general inability or unwillingness of industry to collect,

maintain, and share quality exposure information. Although the Supreme Court, in the benzene decision, determined that "OSHA is not required to support its findings that a significant risk exists with anything approaching scientific certainty,"[104] the PEL revision process is sufficiently difficult and time-consuming that OSHA has managed to modify only eleven PELs.[105] Attempting to compensate for a lack of progress, in 1989 OSHA issued a comprehensive air contaminants standard that modified more than 400 PELs. Because of objections from both industry and labor, a court of appeals nullified the revised PELs.[106] As a result, the vast majority of the current PELs are based on criteria that are approaching 30 years of age. OSHA[18] recently announced its intention once again to start the PEL revision process and solicited comments about the selection of target chemicals, appropriate risk assessment methods for carcinogens and noncarcinogens, and determination of significant risk for carcinogens and noncarcinogens. OSHA listed 20 chemicals as candidates for revision and intends to revise the PELs for 20 or so substances at a time, thus avoiding the problems encountered during the earlier revision effort.

While OSHA contemplates revising the PELs, Congress is considering proposals to make risk assessment at the federal level more rigorous and thus presumably more defensible.[9] Because the PEL revision process is likely to be slow at best, resulting in significant delays before more protective PELs are adopted,[107] enlightened companies are likely to rely on the more current TLVs or to devise corporate OELs that use the latest epidemiologic and toxicologic data.

OSHA is compelled, for both practical and legal purposes, to define the PELs as values never to be exceeded. It is easy to envision the multitude of arguments that a company could make if OSHA attempted to issue a citation for violation of a TWA PEL defined as the upper limit for long-term or lifetime mean exposure. Similarly, if TWA PELs were defined as the 95th percentile exposure, many employers would be inclined to claim that any overexposure measured during an OSHA health inspection was one of the "allowed" overexposures.[108] However, because of the uncertainty in every exposure measurement, due to sampling and analytic error (variability), OSHA does not simply issue a citation whenever a measurement collected by a compliance officer exceeds the PEL. OSHA's policy is to calculate the lower confidence limit for each measurement and to issue a citation only when the lower confidence limit exceeds the PEL.[109] If the company has historical exposure data, the OSHA compliance officer is instructed[109] to "review the long-term pattern and compare it to the [OSHA] results. When OSHA's samples fit the long-term pattern, it helps to support the compliance determination. When OSHA's results differ substantially from the historical pattern, the [compliance officer] should investigate the cause of this difference and perhaps conduct additional sampling."

This practice underscores the importance of an employer's collecting and maintaining sufficient, recent exposure data to demonstrate convincingly that exposures are usually controlled (see previous discussion of models of compliance). However, the "outlier" excuse will not prevail if no historical exposure data exist or the data are dated or not comparable to OSHA's.[110] In such cases, the compliance officer will undoubtedly issue a citation and require the employer to evaluate the potential problem and to take corrective steps if necessary. OSHA's citation philosophy is entirely compatible with the previous discussion of the interpretation of one or more overexposures.

OSHA has considered and rejected as impractical industry proposals to define new TWA PELs as long-term values.[7] However, OSHA[7] noted in the preamble to the 1987 benzene standard:

> [T]here is no requirement to control exposures so far below the PEL so as to ensure than absolutely no random exposures exceed the PEL. OSHA's longstanding enforcement policy, in recognition of the existence of the "occasional outlier," is designed to prevent citations being issued under such circumstances.

According to OSHA, excursions above the PEL may occasionally occur in a controlled work environment. In such an environment the true long-term mean exposure for each employee will be below the PEL. How far below is not specified, but in regard to the 1987 benzene standard, OSHA[7] stated:

> (1) [V]irtually all employers keep long term average exposures under the PEL by a margin and where feasible under the action level with a margin." (p. 34508)
>
> (2) Employers generally keep their exposures on average somewhat under the PEL so if the measurement is high on the day of inspection, the measured exposures will still be under the PEL. (p. 34535)
>
> (3) In attempting to reduce the possibility of a random exposure exceeding the . . . PEL, employers will generally reduce average exposures to well below [the PEL]. (p. 34537)

Regarding the 1978 lead PEL, OSHA[96] stated:

> OSHA recognizes that there will be day-to-day variability in airborne lead exposure experienced by a single employee. The permissible exposure limit is a maximum allowable value which is not to be exceeded: hence exposure must be controlled to an average value well below the permissible exposure limit in order to remain in compliance.

If one accepts the proposition that an "occasional outlier" implies that no more than 1 in 20 single-shift TWAs exceeds the PEL and assumes that exposures are lognormally distributed with characteristic GSDs in the range of 1.5–3, the true long-term mean for a "minimally controlled" work environment will be in range of 0.30 • PEL to 0.56 • PEL (for example, see Fig. 2.) Interested readers should review OSHA's well-conceived but hardly noticed "non-mandatory" appendix to the 1992 formaldehyde standard.[46] It provides considerable common-sense guidance for the design and implementation of an exposure monitoring program.

OSHA's mandatory monitoring requirements were designed to establish baseline information about employee exposures. Only under the "best of circumstances [will] all questions regarding employee exposure be answered."[46] For example, if exposures for all employees are truly controlled or better, the application of OSHA's mandatory requirements almost certainly will result in the employer's concluding that exposures are acceptable. However, low exposures collected on a single day or across several days do not automatically guarantee the employer that the workplace is currently or will continue to remain in compliance with a TWA PEL. Even poorly-controlled work environments often have a majority of exposures less than the PEL. The employer should be aware that in such circumstances strict application of the minimalistic mandatory requirements for exposure monitoring often lead the mistaken conclusion that exposures, in general, are acceptable.

National Institute for Occupational Safety and Health

NIOSH was created by the 1970 OSHAct primarily to "develop and establish recommended occupational safety and health standards."[22] Since then NIOSH has developed and issued over 100 "criteria documents" recommending new or revised exposure limits. These limits are called recommended exposure limits (RELs). They are not legal limits but recommendations to OSHA and occasionally the Mine Safety and Health Administration (MSHA). With one exception (radon), NIOSH TWA

RELs are defined as upper limits for single-shift exposures. Most of NIOSH's early RELs were health-based; that is, set so that the overwhelming majority of exposed workers are protected, without regard to feasibility. According to NIOSH's current policy, RELs "will be based on risk evaluations using human or animal health effects data, and on an assessment of what levels can be feasibly achieved by engineering controls and measured by analytical techniques. To the extent feasible, NIOSH will project not only a no-effect exposure, but also exposure levels at which there may be residual risks. This policy applies to all workplace hazards, including carcinogens."[111]

NIOSH's criteria document on respirable coal mine dust[13] illustrates a risk assessment process similar to that recommended by the NRC.[12] NIOSH considered epidemiology, sampling and analytic feasibility, and technologic feasibility before issuing a recommendation. NIOSH determined that a long-term average exposure of 0.5 mg/m^3 was both reasonably consistent with a target significant risk level and feasible. NIOSH also determined, using estimates of within-occupation variability for underground coal mining, that the 95th percentile daily exposure (i.e., single-shift TWA) for a miner whose long-term average exposure is 0.5 mg/m^3 will be approximately 1 mg/m^3. Therefore, for purposes of risk management, NIOSH[13] recommended an upper limit of 1 mg/m^3 for each single-shift TWA. NIOSH recognized that the underground mining environment can be highly variable and recommended, as part of a proper risk management program, that exposures be monitored on a regular basis:

> (1) Exposure sampling should be periodic and should occur frequently enough that a significant and deleterious change in the contaminant generation process or the exposure controls is not permitted to persist.
>
> (2) The objective of an effective exposure sampling strategy is to periodically obtain sufficient, valid, and representative exposure estimates so that the work environment is reliably classified as either acceptable or unacceptable.

NIOSH cautioned that this REL may not be sufficiently protective to prevent all occupational respiratory disease among coal miners exposed for a working lifetime and therefore recommended additional measures to reduce the risk of disease: participation of miners in medical screening and surveillance programs, development and application of improved dust control techniques, use of personal protective equipment as an interim measure if exposures cannot be adequately controlled, and routine monitoring of exposures. NIOSH provided sufficient information so that, in principle, either the indirect or direct between-shift control model could be used to develop a statistically rigorous exposure assessment strategy; that is, both long-term and daily risk management goals are clearly stated. However, NIOSH's other recommendations in the document for exposure sampling and data interpretation are consistent with the commonly applied indirect control model.

Corporate and Other Occupational Exposure Levels

Only a relative handful of the tens of thousands of substances and mixtures encountered in industrial operations have OELs. Many corporations that produce or use chemicals without OELs find themselves compelled by both ethical and liability considerations to develop corporate occupational exposure limits.[10,11] (Industrial hygienists should review Harris[112] for a discussion of professional ethics and the use of new toxicologic and epidemiologic information.) Paustenbach[10] recommends that companies that set corporate OELs accept three propositions: (1) OELs are needed whenever employees are exposed to toxic agents; (2) the company should fully document the rationale for establishing a corporate OEL; and (3) "tentative" corporate

OELs should be set even if adequate toxicologic and epidemiologic data are not available.

Producers of specialty chemicals, byproducts, intermediate chemicals, and pharmaceuticals[113] regularly set internal or corporate OELs. The process is usually multidisciplinary, involving industrial hygienists, toxicologists, physicians, and epidemiologists. Once the corporate OEL is set by the corporate risk assessors, the plant risk manager or industrial hygienist should treat it like any legal or authoritative OEL and effectively manage employee risks by controlling exposures to the extent required.

A PHILOSOPHY FOR OCCUPATIONAL EXPOSURE MANAGEMENT

Management by a physician of a patient's risk of cholesterol-related diseases is analogous to the practice of exposure management by an industrial hygienist. We are all familiar with the often encountered target upper limit for total blood cholesterol of 200 mg/dl. This limit was developed using population-based studies and represents a target average value that cholesterol risk managers at the National Institutes of Health would like to see for the U.S. population.[114] However, for purposes of individual risk management, the NIH recommends that each individual maintain total blood cholesterol below 200 mg/dl. As the cholesterol risk manager for a specific patient, a physician is concerned primarily with that patient's current exposure to excessive cholesterol. The physician has little knowledge of how well a patient's cholesterol levels were managed by previous health care providers, nor can the physician predict the quality of care provided by the responsible physician in the future. What the physician can do, however, is to ensure that during the time that the patient is under his or her care, the risks associated with elevated cholesterol levels are properly managed, i.e., minimized. The physician does so through the use of proper and regular tests, comparison of each cholesterol measurement with a target value corresponding to an acceptable level of risk, and regular issuance of sound advice based on the current measurement. Assuming that the patient visits the physician once per year, the goal of the physician is to ensure that the cholesterol level of each patient is less than or equal to the target value for each year of observation. Given the recommendations of authoritative organizations such as the NIH, it would be inappropriate, in fact wrong, for the physician to average a current high cholesterol measurement with low past measurements and compare the average with the target value. The current high value indicates that a change of some sort has occurred and needs attention.[115]

Like the personal physician, the plant industrial hygienist is responsible for the proper management of the risk experienced by each employee. The industrial hygienist usually has little knowledge of how well risk was managed in the past when others were responsible. Past exposure data are usually sparse at best and almost certainly unavailable for employees with work histories elsewhere. In any case, exposures in the distant past have little predictive value regarding future exposures. In addition, the industrial hygienist cannot predict how well others will manage the exposures of the employee after the industrial hygienist leaves or the employee moves to other jobs or worksites. What the industrial hygienist can do, however, is to act as the steward of each employee's good health by ensuring that each employee's current risk is properly managed during the time that the industrial hygienist is employed by the company and the employee is in his or her sphere of responsibility. Consequently, current exposure data have the best predictive value regarding the

continued quality of risk management for an employee or group of similarly exposed employees. As in the cholesterol example above, a current high exposure measurement suggests that a change of some sort has occurred and should be investigated (see the earlier discussion of interpretation of single overexposures).

CURRENT TRENDS

Several current trends have the potential to affect the practice of industrial hygiene:

- Development of hybrid exposure assessment strategies
- Development of occupational exposure databases
- Increased capability to collect exposure data
- Increased use of formal statistical tests
- Statistically defined OELs
- Generic "performance-based" exposure assessment standards

It has long been recognized that data collected solely for the purpose of determining compliance usually reflect the exposures of the maximum risk employees within each exposure group. Such data may present occupational epidemiologists with a distorted picture of the exposure experience of each exposure group. Many researchers are promoting the routine collection of surveillance exposure data from all occupations in addition to the measurements typically collected to determine current compliance.[28,36,116] Because the shape of an exposure-response curve is most contentious at the low end, such data could be extremely useful in determining the often critical low exposure cells in the epidemiologist's job-exposure matrix. Hybrid exposure sampling strategies—that is, strategies that permit the collection of exposure information for compliance and surveillance or research purposes—should become more common in the future and eventually lead to more accurate exposure-response analyses.

Farsighted researchers are envisioning occupational exposure databases that cover a multitude of substances and span across companies and industries.[117,118] Such databases could be used to generate research hypotheses, to evaluate the efficacy of different types of controls, and to provide accurate industrywide exposure data for trade organizations and standards-setting organizations, among other uses.

The current state-of-the-art exposure measurement model is as follows: *For purposes of measuring worker exposure across a single shift it is sufficient to place a reasonably accurate exposure measuring device on the worker, within the worker's breathing zone, and have it operate for nearly the full shift.* Two trends during the 1960s led to this model: (1) the movement from area to personal exposure measurements and (2) the move from short-term (i.e., less than 30 minutes) to full-shift (or nearly full-shift) sampling.[48] These trends resulted primarily from the development of battery-powered personal sampling pumps. For particulate substances the development of sensitive analytic balances and improved filtration materials permitted industrial hygienists to shift from measuring particles per unit volume to measuring particulate mass per unit volume. During the 1970s a major concern on the part of NIOSH and OSHA was to ensure that reasonably accurate sampling and analytic methods were available for measuring the substances regulated by OSHA. Because of the efforts of NIOSH, OSHA, and many company and private laboratories, the majority of regulated substances now have sampling and analytic methods with coefficients of variation less than 0.1. However, even imperfect or imprecise measures of exposure, such those for asbestos, crystalline silica, cotton dust, or coal tar pitch volatiles and coke oven emissions, can be used effectively for risk management.

Since the early 1970s the improvements have been important, but subtle: improvements in the reliability of sampling pumps and analytic method sensitivity and development of automated analytic techniques. Researchers have recently developed data acquisition systems suited for task analysis or the process of determining which task (i.e., component of a job) or work practice contributes most to the worker's overall exposure.[119] The increased use of direct reading instruments coupled with data storage devices, the development of electronic sensors for specific chemicals, and the increased availability of passive dosimeters provide industrial hygienists the means to characterize more accurately exposures for a larger percentage of the workforce and may eventually lead to the inexpensive and accurate characterization of within-shift and between-shift exposure profiles for nearly all workers.[120]

In the 1960s and well into the 1970s data analysis often consisted of the comparison of one or several TWA estimates with the TWA OEL.[40,48,81,83,85] Consequently, formal statistical tests were used in a compliance context to determine whether a single TWA was significantly above or below the TWA OEL. Employers determined the acceptability of a work environment by collecting one or several measurements from one or more maximum risk employees and applying simple decision rules.[40] As the quantity of data increased, industrial hygienists have adopted ever more sophisticated and statistically defensible data analysis procedures,[36,44,47,48,55,71,121] although the need for simple decision rules remains.[47,49,52,55]

The AIHA[122] recently issued a white paper on generic exposure assessment standards and recommended that OSHA issue "clear statistical definitions of overexposure." Stated differently and in a more positive manner, OSHA should issue a clear statistical definition of compliance. As previously discussed, NIOSH recently took a step in this direction in a criteria document about respirable coal mine dust by recommending a single-shift limit and indicating the long-term mean exposure that should result when the single-shift limit is met on the majority of work shifts for each individual coal miner.[13] It would be helpful if regulatory agencies and authoritative bodies would state clearly both proximate and long-range goals of an OEL. In this manner the industrial hygienist could acquire a clear understanding of the logic underlying the OEL and an appreciation for the range in which current exposures should fall for a work environment to be considered currently controlled for each worker and the range in which individual long-term average exposures should fall so that the long-range goal of the OEL is truly realized.

In 1988 OSHA[123] issued an "advanced notice of proposed rulemaking" regarding a proposal to issue a "generic exposure assessment standard." This standard would apply to the majority of PELs, which have no specific requirements for exposure sampling strategies and data interpretation. OSHA anticipates that the generic standard will be performance-based; that is, it will set out broad goals and leave it to individual companies to design exposure sampling strategies and decision logics that are consistent with the performance goals yet tailored for specific work environments. To date there has been little progress toward a final standard, even though this announcement led to considerable interest and activity.[122,124,125]

NOTES

1. Monson RR: Occupational Epidemiology, 2nd ed. Boca Rotan, FL, CRC Press, 1990, p 244.
2. Burke TA: The proper role of epidemiology in regulatory risk assessment: Reaction from a regulator's perspective. In Graham JD (ed): The Role of Epidemiology in Regulatory Risk Assessment. 1995.
3. Industrial hygienist means a professional qualified by education, training, and experience to anticipate, recognize, evaluate, and develop controls for occupational health hazards.[68]

4. Many of the concepts and observations in this chapter can be generally applied to irritants, acutely toxic substances, and substances that are not usually considered chronic disease agents but have (TWA) OELs as control limits.
5. Paustenbach DJ: Occupational exposure limits: Their critical role in preventive medicine and risk management [editorial]. Am Ind Hyg Assoc J 51:A332–A336, 1990.
6. OSHA's single substance, 6b standards and NIOSH's RELs consist additionally of minimal exposure monitoring, exposure control, respiratory protection, and medical monitoring requirements and recommendations, respectively. The combination of an occupational exposure limit with these additional requirements can enhance the level of protection afforded the individual workers.[7,68] However, such complete standards are usually not recommended by nonregulatory risk assessors.
7. OSHA (Occupational Safety and Health Administration): Occupational exposure to benzene: Final rule. Fed Reg 52(176):34460–34578, 1987.
8. The number of measurements collected during a single shift can vary from a single, full-shift measurement to several consecutive, partial-shift measurements as long as the TWA is accurately estimated.
9. Finkel AM: Commentary: Who's exaggerating? Discover May:48–54, 1996.
10. Paustenbach DJ: Occupational exposure limits, pharmacokinetics, and unusual work schedules. In Harris RL, Cralley LJ, Cralley LV (eds): Patty's Industrial Hygiene and Toxicology. 3rd ed, volume 3. New York, John Wiley & Sons, 1994.
11. Paustenbach D, Langner R: Corporate occupational exposure limits: The current state of affairs. Am Ind Hyg Assoc J 47:809–818, 1986.
12. National Research Council : Risk Assessment in the Federal Government: Managing the Process. Washington, DC, National Academy Press, 1983.
13. National Institute for Occupational Safety and Health: Criteria for a Recommended Standard—Occupational Exposure to Respirable Coal Mine Dust. Washington, DC, National Institute for Occupational Safety and Health, DHHS (NIOSH) publication no. 95-106, 1995.
14. This refers to the ability to measure accurately concentrations of respirable coal mine dust at or near the REL.
15. Paustenbach DJ: Health risk assessment and the practice of industrial hygiene. Am Ind Hyg Assoc J 51:339–351, 1990.
16. Leung H, Paustenbach DJ: Assessing health risks in the workplace: A study of 2,3,7,8-tetrachlorodibenzo-p-dioxin. In Paustenbach DJ (ed): The Risk Assessment of Environmental and Human Health Hazards: A Textbook of Case Studies. New York, Wiley-Interscience, 1989.
17. Hallenbeck WH: Quantitative Risk Assessment for Environmental and Occupational Health. 2nd ed. Ann Arbor, MI, Lewis Publishers, 1993.
18. Some industrial hygienists believe that they should not be classified as risk managers but instead as risk assessors. This is because, in most cases, the prerogative to implement or augment controls resides solely with the plant manager. My view is that industrial hygienists should be considered not only part of a company's occupational exposure risk management program but also an integral, critical part. A "risk assessment," as the term is commonly used in government and academia when considering occupational exposures, typically involves the determination, based on an analysis of exposure and health effects data from a cohort, of the probability of an adverse outcome given a specific level of working lifetime average or cumulative exposure. It is difficult, if not impossible, to determine this probability for any specific employee.
19. McMahan S, Meyer J: Communication of risk information to workers and managers: Do industrial hygienists differ in their communication techniques. Am Ind Hyg Assoc J 57:186–190, 1996.
20. Adkins CE, et al: Letter to the editor. Appl Occup Environ Hygiene 5:748–750, 1990.
21. Roach SA: A most rational basis for air sampling programmes. Ann Occup Hyg 20:65–84, 1977.
22. Occupational Safety and Health Act of 1970 (OSHAct): Public Law 91-596, 1970.
23. Federal Mine Safety and Health Act of 1977 (FMSHAct): Public Law 91-173, 1977.
24. "Acceptable risk" or "de minimis" risk for occupational risk factors has yet to be quantified.
25. Occupational Safety and Health Administration: Updating permissible exposure limits (PELs) for air contaminants; Meeting. Fed Reg 61:1947–1950, 1996.
26. Alavanja MCR, Brown C, Spirtas R, Gomez M: Risk assessment for carcinogens: A comparison of approaches of the ACGIH and EPA. Appl Occup Environ Hygiene 5:510–517, 1990.
27. Peak exposures or sustained periods of high exposures may be important in the etiology of many occupational chronic diseases. However, exposure histories are nearly always incomplete. Consequently, the epidemiologist by default uses the estimates of long-term exposure in exposure-response analyses.
28. Park CN, Hawkins NC: Cancer risk assessment. In Cralley LJ, Cralley LV, Bus JS (eds): Patty's Industrial Hygiene and Toxicology. 3rd ed, vol 3. New York, John Wiley & Sons,1995.

29. Drinker P , Hatch T: Industrial Dust—Hygienic Significance, Measurement, and Control. 2nd ed. New York, McGraw-Hill, 1954.
30. Roach SA: A more rational basis for air sampling programs. Am Ind Hyg Assoc J 27:1–12, 1966.
31. Roach SA: Health Risks from Hazardous Substances at Work—Assessment, Evaluation, and Control. New York, Pergamon Press,1992.
32. Tebbens BD, Spear RC: Quality control of work environments. Am Ind Hyg Assoc J 32:546–551, 1971.
33. Esmen NA: A distribution-free double-sampling method for exposure assessment. Appl Occup Environ Hygiene 7:613–621, 1992.
34. An "observation period" or "sample period"[52] is some arbitrary but manageable period, typically no more than a year.[36,52] Longer observation intervals are justified only when exposures have been demonstrated to be "minimal" (i.e., only infrequently exceed one-tenth of the TWA OEL)[31] and the processes that generate and control exposures are reasonably stable. The frequency of periodic monitoring for work environments that are nominally in compliance varies, depending on the exposure history of the work environment, the type of controls in place (e.g., total or partial enclosure, local or general exhaust ventilation), and the likelihood of significant change since the last evaluation (largely a judgment call).[31,36,52,53] After a baseline evaluation periodic evaluations should occur at least yearly. If, after several years, a consistent history of well-controlled exposures or better can be demonstrated, the employer may be justified in reducing the number of measurements collected and/or the frequency of sampling (for example, to once every two or three years, depending on the circumstances).
35. Rappaport SM, Selvin S, Roach SA: A strategy for assessing exposures with reference to multiple limits. Appl Ind Hygiene 3:310–315, 1988.
36. Hawkins NC, Norwood SK, Rock JC (eds): A Strategy for Occupational Exposure Assessment. Fairview, VA, American Industrial Hygiene Association, 1991.
37. Often an exposure assessment strategy will have multiple purposes. Exposures may also be collected to evaluate point sources of contaminants, to determine the efficacy of controls, or for research (epidemiologic) purposes.[29,47,116,121]
38. An exposure monitoring program or exposure assessment strategy is composed of two parts: an exposure sampling strategy and a decision logic. The exposure sampling strategy specifies the process for selecting whom to monitor, when to monitor, how many TWA measurements to collect, and how often to repeat this process. The decision logic specifies the procedure for interpreting the exposure data and deciding whether or not the work environment is currently acceptable or unacceptable.
39. "Significant" exposures are usually interpreted to be those above one-tenth of the OEL.[31,48,71]
40. Leidel NA, Busch KA, Lynch JR: Occupational Exposure Sampling Strategy Manual. National Institute for Occupational Safety and Health publication no. 77-173 (available from the National Technical Information Service, publication no. PB274792), 1977.
41. The decision logic was simple: If the first measurement is less than half the PEL, conclude that the work environment is acceptable for the exposure group represented by the MRE. If the first measurement is above the PEL, conclude that the work environment is unacceptable and take corrective action. Otherwise, collect additional measurements at specified intervals until either two consecutive measurements are less than half the PEL (and conclude that the exposures are acceptable) or any single measurement is above the PEL (and conclude that exposures are unacceptable and take appropriate actions to reduce exposures).
42. Tuggle RM: The NIOSH decision scheme. Am Ind Hyg Assoc J 42:493–498, 1981.
43. Rappaport SM: The rules of the game: An analysis of OSHA's enforcement strategy. Am J Ind Med 6:291–303, 1984.
44. Rappaport SM: Interpreting levels of exposures to chemical agents. In Harris RL, Cralley LJ, Cralley LV (eds): Patty's Industrial Hygiene and Toxicology. 3rd ed, vol 3. New York, John Wiley & Sons, 1994.
45. OSHA frequently uses the term "representative employees" in its standards for specific substances [6(b) standards]. If there are known or readily discernable differences in the exposure potential of the employees in an exposure group, the "representative employee" can be considered equivalent to NIOSH's concept of the "maximum risk employee."[7,46] Otherwise, a random sampling strategy should be devised so that there is a high likelihood that the higher exposed employees are represented in the sample.
46. Occupational Safety and Health Administration: Code of Federal Regulations 29, Part 1910.1048 Formaldehyde (Appendices A and B), 1994.[46]
47. Guest IG, Cherrie JW, Gardner RJ, Money CD: Sampling Strategies for Airborne Contaminants in the Workplace. British Occupational Hygiene Society Technical Guide No. 11 (ISBN 0 948237 14 7). Leeds, H and H Scientific Consultants, 1993.

48. Ayer HE: Occupational air sampling strategies. In Hering SV (ed): Air Sampling Instruments for Evaluation of Atmospheric Contaminants. 7th ed. Cincinnati, American Conference of Governmental Industrial Hygienists,1989.
49. Lynch JR: Measurement of worker exposure. In Harris RL, Cralley LJ, Cralley LV (eds): Patty's Industrial Hygiene and Toxicology. 3rd ed, vol 3. New York, John Wiley & Sons, 1994.
50. Corn M, Esmen NA: Workplace exposure zones for classification of employee exposures to physical and chemical agents. Am Ind Hyg Assoc J 40:47–57, 1979.
51. Esmen NA: Mathematical basis for an efficient sampling strategy. In Marple VA, Liu BYU (eds): Aerosols in the Mining and Industrial Work Environment. Vol I. 1983.
52. Still KR, Wells B: Quantitative industrial hygiene programs: Workplace monitoring. Appl Ind Hygiene 4:F14–F17, 1989.
53. Corn M: Sampling strategies for prospective surveillance: Overview and future directions. In Industrial Hygiene Science Series—Advances in Air Sampling. Ann Arbor, MI, Lewis Publishers, 1988.
54. The Committee allows that the industrial hygienist may select the "most exposed worker" when determining whether an HEG is in compliance with a government standard.
55. CEN (Comité Européen de Normalisation): Workplace atmospheres—Guidance for the assessment of exposure by inhalation of chemical agents for comparison with limit values and measurement strategy. European Standard EN 689, effective no later than Aug 1995 (Feb 1995).
56. "[I]f an individual exposure is less than half or greater than twice the arithmetic mean [for the HEG], the relevant work factors should be closely re-examined to determine whether the assumption of homogeneity was correct."[55]
57. Kromhout H, Symanski E, and Rappaport SM: A comprehensive evaluation of within- and between-worker components of occupational exposure to chemical agents. Ann Occup Hyg 37:253-270, 1993.
58. Rappaport SM, Kromhout H,Symanski E: Variation of exposure between workers in homogeneous exposure groups. Am Ind Hyg Assoc J 54:654–662, 1993.
59. Such data include repeat measurements randomly collected from a random sample of workers within each exposure group, which then could be analyzed using ANOVA techniques.
60. Efficiency refers to the ability to come to a decision, right or wrong, with a limited number of measurements.
61. Tuggle RM: Assessment of occupational exposure using one-sided tolerance limits. Am Ind Hyg Assoc J 43:338–346, 1982.
62. Any LTA OEL should have a corresponding TWA OEL to prevent abuse of the LTA OEL concept. For example, it is inappropriate to expose workers to 12 times the LTA OEL for 1 month followed by 11 months of zero exposure.
63. Roach[31] recommended a similar goal: "A [reasonably homogeneous] job-exposure group which is within 0.1–1.0 x exposure limit band but yields results consistently below one-third the exposure limit could be sampled at a reduced frequency, namely once every two months" (p 327).
64. Roach SA, Rappaport SM: But they are not thresholds: A critical analysis of the documentation of threshold limit values. Am J Ind Med 17:727–753, 1990.
65. The effective OEL, or citation value, is the OEL plus an allowance for sampling and analytical error (SAE). SAE is calculated using the total coefficient of variation (CVT) for the sampling and analytical method. For a typical CVT of 0.1 the allowance is easily calculated: SAE = (1.645 • CVT • OEL).
66. Spear RC, Selvin S, Schulman J,Francis M: Benzene exposure in the petroleum refining industry. Appl Ind Hygiene 2:155–163, 1987.
67. Rappaport SM, Lyles RH, Kupper LL: An exposure-assessment strategy accounting for within- and between-worker sources of variability. Ann Occup Hyg 39:469–495, 1995.
68. Occupational Safety and Health Administration: Occupational exposure to asbestos; final rule. Fed Reg 59:40964–41158 (p 41058), 1994.
69. The AIHA Exposure Assessment Strategies Committee monograph[36] was directed at persuading industrial hygienists to collect sufficient measurements for each homogeneous exposure group (HEG) so that the underlying parameters of the group exposure distribution are reliably estimated. These parameter estimates are then used in various statistical procedures to assess the acceptability of the exposure distribution for the HEG.
70. Cope RF, Pancamo BP, Rinehart WE, Haar GLT: Personnel monitoring for tetraalkyl lead in the workplace. Am Ind Hyg Assoc J 40:372–379, 1979.
71. Rock JC: Occupational air sampling strategies. In Cohen BS, Hering SV (eds): Air Sampling Instruments for Evaluation of Atmospheric Contaminants. 8th ed. Cincinnati, American Conference of Governmental Industrial Hygienists, 1995.

72. Nicas M, Simmons BP, Spear RC: Environmental versus analytical variability in exposure measurements. Am Ind Hyg Assoc J 52:553–557, 1991.
73. The survey notes should be evaluated for unusual occurrences (e.g., spills, temporary control equipment breakdowns) that are unlikely to recur or for systematic changes in the work environment (e.g., increased production level, process changes, decreased efficiency of the control equipment, introduction of new or untrained workers, changes in work practices).
74. In the preamble to the 1987 benzene revised PEL,[7] OSHA recommended that exposure data more than 1 year old be given little or no weight in evaluating the current exposure management practices. In the preamble to the 1992 cadmium revised PEL, OSHA stated that when using "historic monitoring" results to meet the "initial monitoring" requirements of the new standard, the employer must meet two conditions: (1) the historic exposure conditions must be similar to current conditions and the measurement method must conform to the requirements of the standard, and (2) monitoring must have been conducted "within 12 months prior to the publication date of this standard" (Fed Reg 57(178):42337, Sept 14, 1992).
75. Ziem GE, Castleman BI: Threshold limit values: Historical perspectives and current practice. J Occup Med 31:910–918, 1989.
76. Castleman BI, Ziem GE: American Conference of Governmental Industrial Hygienists: Low threshold credibility. Am J Ind Med 26:133–143, 1994.
77. American Conference of Governmental Industrial Hygienists: Threshold Limit Values: A more balanced appraisal. Appl Occup Environ Hygiene 5:340–344, 1990.
78. Corn M: Regulations, standards, and occupational hygiene within the U.S.A. in the 1980s. Ann Occup Hyg 27:91–105, 1983.
79. Corn M: Historical perspective on approaches to estimation of inhalation risk by air sampling. Am J Ind Med 21:113–123, 1992.
80. Stokinger HE: Threshold Limit Values. Dangerous Properties of Industrial Materials Report. May/June pp 8–13, 1981.
81. Stokinger HE: Threshold limits and maximum acceptable concentrations: Their definition and interpretation. Am Ind Hyg Assoc J 23:45–47, 1962 (see also a nearly identical article in Arch Environ Health 4:115–117, 1962).
82. Stokinger HE: Modus operandi of threshold limits committee of ACGIH. In Transactions of the Twenty-sixth Annual Meeting of the American Conference of Governmental Industrial Hygienists 26:23–29, 1964.
83. Stokinger HE: Industrial air standards—theory and practice. J Occup Med 15:429–431, 1973.
84. Stokinger HE: Intended use and application of the TLVs. In Transactions of the Thirty-third Annual Meeting of the American Conference of Governmental Industrial Hygienists, 33:113–116, 1971.
85. Roach SA, Baier EJ, Ayer HE, Harris RL: Testing compliance with threshold limit values for respirable dusts. Am Ind Hyg Assoc J 28:543–553, 1967.
86. Readers should be aware, when reading these references, that in the 1960s and early 1970s the usual practice was to use several short-term, partial shift measurements to estimate a single TWA.[48,85]
87. American Conference of Governmental Industrial Hygienists: Threshold Limit Values for Air-borne Contaminants for 1968, Recommended and Intended Values, 1968.
88. Nearly identical wording has been included in the introduction of every TLV booklet since 1968, including the current 1995–1996 booklet.
89. Stokinger HE: Current problems of setting occupational exposure standards. Arch Environ Health 19:277–280, 1969.
90. In 1969 and 1971 Stokinger lamented the fact that occasionally the "factory inspector" and "legal profession" interpreted high short-term measurements (i.e., partial shift, the common type of measurement prior to the 1970s) as evidence that the TWA TLV had been breached or as "proof or disproof of an existing disease or physical condition." Stokinger noted that such short-term measurements were best compared to ceiling values and the then newly developed short-term limits and not to the TWA TLV's.
91. American Conference of Governmental Industrial Hygienists: 1995–1996 Threshold Limit Values (TLVs) for Chemical Substances and Physical Agents and Biological Exposure Indices (BEIs). ACGIH, Cincinnati, 1995.
92. Stokinger also mentioned that TLVs should not be used as a measure of "relative index of toxicity." The strength of the data for each TLV vary, the site and mode of action vary, and, most importantly, the actual risk depends on the likelihood and severity of exposure. (It also may be assumed that the exposure-response curves for different substances will have different shapes or slopes.)
93. Brief RS , Scala RA: Occupational exposure limits for novel work schedules. Am Ind Hyg Assoc J 36:467–469, 1975.

94. American Conference of Governmental Industrial Hygienists: Documentation of the Threshold Limit Values and Biological Exposure Indices. 6th ed. ACGIH, Cincinnati, 1991.
95. Consider your response if your physician announced that your blood cholesterol was 400 mg/dl but that you should not be concerned because the average across all the patients that day was equal to or less than the goal of 200 mg/dl.
96. Occupational Safety and Health Administration: Occupational exposure to lead; final standard. Fed Reg 43(220):52952–53014, 1978.
97. Paull JM: The origin and basis of threshold limit values. Am J Ind Med 5:227–238, 1984.
98. ACGIH also recommends "ceiling" limits for fast-acting substances. A TLV-C represents "the concentration that should not be exceeded during any part of the working exposure." Exposures should be measured using an "instantaneous" direct reading instrument or averaged over a period not longer than 15 minutes.[91]
99. American Conference of Governmental Industrial Hygienists: Documentation of the Threshold Limit Values for Substances in Workroom Air. 3rd ed. ACGIH, Cincinnati, 1971.
100. Within-shift excursion factors make little or no sense if the TWA TLV is truly an upper limit for the long-term, lifetime average exposure of each worker.
101. Silva P: TLVs to protect "nearly all workers." Appl Occup Environ Hygiene 1:49–53, 1986.
102. American Industrial Hygiene Association: Workplace environmental exposure level guides. Am Ind Hyg Assoc J 55:71–72, 1994.
103. American Industrial Hygiene Association: AIHA WEEL Committee Charter, May 11, 1994.
104. U.S. Supreme Court: *Industrial Union Department, AFL-CIO v. American Petroleum Institute et al.*, case nos. 78-911, 78-1036. Supreme Court Reporter 100:2871, 1980.
105. Asbestos, vinyl chloride, inorganic arsenic, lead, benzene, coke oven emissions, cotton dust, 1,2-dibromo-3-chloropropane, acrylonitrile, ethylene oxide, and formaldehyde.
106. de la Cruz PL, Sarvadi DG: OSHA PELs: Where do we go from here? Am Ind Hyg Assoc J 55:894–900, 1994.
107. Nicholson WJ, Landrigan PJ: Quantitative assessment of lives lost due to delay in the regulation of occupational exposure to benzene. Environ Health Perspect 82:185–188, 1989.
108. Imagine, if you will, the excuses that could be made if speed limits were legally defined as "65 mph and under, 95% of the time" or "65 mph, on average." Enforcement would be difficult indeed.
109. Occupational Safety and Health Administration: OSHA Technical Manual (OTM), Directive TED 1.15, September 22, 1995.
110. Historical measurements will not be comparable to OSHA's full-shift compliance measurements if the measurements represent grab-samples or short-term exposures; were collected from substantially different shifts, processes, operations, or occupations; or process changes have occurred.
111. National Institute for Occupational Safety and Health: NIOSH Recommended Exposure Limit Policy, May 24, 1996.
112. Harris RL: Information, risk, and professional ethics. Am Ind Hyg Assoc J 47:67–71, 1986.
113. Naumann BD, et al.: Performance-based exposure control limits for pharmaceutical active ingredients. Am Ind Hyg Assoc J 57:33–42, 1996.
114. National Institutes of Health: Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II). NIH publication no. 93-3095, 1993.
115. There is one aspect of cholesterol risk management that does not easily translate to the workplace. The NIH recommends that physicians encourage patients with a record of high cholesterol to reduce their cholesterol level considerably below the target value to balance the excessive exposures. With the exception of coal miners (who can be transferred to low dust areas based on evidence that pneumoconiosis has developed) and lead workers (who are transferred to low lead areas on the basis of excessive blood lead levels), this concept is not usually practiced by occupational health risk managers.
116. Harris RL: Guideline for Collection of Industrial Hygiene Exposure Assessment Data for Epidemiologic Use. Prepared for the Chemical Manufacturers Association, 1993.
117. Gomez MR, Rawls G: Conference on occupational exposure databases: A report and look at the future. Appl Occup Environ Hygiene 10:238–243, 1995.
118. Lippmann M: Exposure data needs in risk assessment and risk management: database information needs. Appl Occup Environ Hygiene 10:244–250, 1995.
119. Gressel MG, Heitbrink WA (eds): Analyzing Workplace Exposures Using Direct Reading Instruments and Video Exposure Monitoring Techniques. National Institute for Occupational Safety and Health publication no. 92-104, 1992.
120. Bierbaum PJ, Doemeny LJ, Smith JP, Abell MT: U.S. approach to air sampling of workplace contaminants: Current basis and future options. Appl Occup Environ Hygiene 8:247–250, 1993.

121. Leidel NA, Busch KA: Statistical design and data analysis requirements. In Harris RL, Cralley LJ, Cralley LV (eds): Patty's Industrial Hygiene and Toxicology. 3rd ed, vol 3. New York, John Wiley & Sons,1994.
122. American Industrial Hygiene Association American Industrial Hygiene Association white paper: A generic exposure assessment standard. Am Ind Hyg Assoc J 55:1009–1012, 1994.
123. Occupational Safety and Health Administration: Generic standard for exposure monitoring—Advance notice of proposed rulemaking. Fed Reg 53:37591–37598, 1988.
124. Organization Resources Counselors, Inc.: A Proposed Generic Workplace Exposure Assessment Standard. Washington, DC, Organization Resources Counselors, Inc., 1992.
125. In a sense the current legal requirements for exposure assessments are performance standards. They represent minimalistic strategies and leave considerable room for voluntary improvement and enhancement. OSHA all but stated this in Appendix B of the 1992 final standard for formaldehyde.[46]