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INTERPRETATION AND USE OF OCCUPATIONAL EXPOSURE LIMITS FOR CHRONIC DISEASE AGENTS

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1 INTRODUCTION

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 when discussing the role of epidemiology in developing federal, state, and local exposure limits:

> "... epidemiology 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 hardly ever 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 said 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* in the sense that they effectively 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 the company level risk managers - industrial hygienists \[a] - to evaluate and control occupational exposures.

In this chapter I will discuss occupational exposure limits (OELs) for chronic disease agents\[b] as both a product of occupational exposure risk assessment and as an essential component of occupational exposure risk management. 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: a concentration, averaging time, and a target (usually the individual worker). Changing any component results in a modified OEL, which for lack of something better will be referred to here as the OEL′ (pronounced "OEL prime"). There are many ways that the OEL can be modified such that the resulting OEL′ will not provide the same level of protection as the original OEL.

a. "*Industrial hygienist* means a professional qualified by education, training, and experience to anticipate, recognize, evaluate, and develop controls for occupational health hazards."[47]

b. 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.

• An OEL for chronic disease agents is often *based* upon a long-term, working lifetime mean exposure that is perceived as being acceptable for *groups* of workers. However, the OEL is *defined* as an upper limit for each single shift time-weighted average 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 can be, and should be, viewed as a quality control problem: the distribution of exposures for each worker should be controlled so that exposures rarely, or at least infrequently, exceed the "upper control limit", i.e., the OEL.

• The measurement and control of occupational exposures is similar in concept to the medical management of non-occupational risk factors, such as elevated cholesterol. Consequently, those charged with risk management (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.

In this chapter I frequently refer to *risk assessors* and *risk managers*. My experience is that these terms are sometimes used interchangeably or are given widely different interpretations or connotations. In order to avoid confusion I adopt the following conventions for the limited purposes of this chapter: First, OELs are the end result of a risk assessment process. Therefore, *risk assessors* are responsible for setting an OEL. Second, *risk managers* are responsible for recognizing, evaluating, and controlling exposures.

2 OCCUPATIONAL EXPOSURE LIMITS and OCCUPATIONAL EPIDEMIOLOGY

Occupational exposure limits are the essential link between the risk assessment process and the practice of risk management.[3] While 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 epidemiological studies that form the basis for an OEL. In many cases the OEL represents, in a compact, distilled form, the relevant occupational epidemiology.

At its most basic, an OEL has three components: a concentration, an averaging time, and a target.\[c] For example, in 1987 the Occupational Safety and Health Administration[4] (OSHA) adopted a Permissible Exposure Limit (PEL) for benzene of 1 ppm and specified the averaging time as a single shift, or 8 hours.\[d] The target (or focus) 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 National Institute for Occupational Safety and Health's (NIOSH) Recommended Exposure Limits (RELs) and the American Conference of Governmental Industrial Hygienists's (ACGIH) Threshold Limit Values (TLVs), are intended, in principle, to be applied to the exposures experienced by *each* employee. It is conceivable, however, that a company has devised, or 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 - the concentration *or* the averaging time *or* the target - 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 TWA measurements to a legal or authoritative OEL where 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 thirty years of age. Considering that Congress may require extensive Federal risk assessments[5] we may soon reach the point of near stagnation when it comes to new or revised Federal OELs. Consequently, industrial hygienists have come to increasingly rely upon 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.[3,6,7]

For purposes of discussion we can divide risk assessors into *governmental* and *non-governmental*. Governmental risk assessors are generally required to implement a comprehensive risk assessment process.[8] A reading of OSHA's preamble to the 1987 benzene standard[4] 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[9] is also worth reviewing as it conforms closely to the current federal risk assessment model in that the REL was based upon a consideration of the epidemiology, sampling and analytical feasibility \[e], and technological feasibility.

Non-governmental risk assessors, such as the ACGIH and the AIHA, often utilize a less rigorous risk assessment process that gives diminished weight to technological feasibility and lacks the mandate to protect "all" workers. Companies

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c. 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.[4,47] However, such 'complete' standards are usually not recommended by non-regulatory risk assessors.

d. The number of measurements collected during a single shift can vary from a single, full-shift measurement to several consecutive, partial-shift measurements, so long as the TWA is accurately estimated.

e. This refers to the ability to accurately measure concentrations of respirable coal mine dust at or near the REL.

producing or using chemicals for which there are no Federal or authoritative OELs often devise interim, company specific OELs.[7]

3 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 upon one's viewpoint. For example, the National Research Council[8] 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.

3.1 Risk Assessment

The National Research Council (NRC)[8] 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[8,10]: (a) Hazard Identification, (b) Dose-Response Assessment, (c) Exposure Assessment, and (d) Risk Characterization. According to the NRC view, 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[11] 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[12] the process of risk assessment involves identifying a potential hazard; characterizing its adverse effects in humans, animals, or in 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 is the view that I adopted for this chapter.

3.2 Risk Management

The NRC[8] 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 present in exposed population and the 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, by 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 that the Federal government or some authoritative organization goes through in order to generate an OEL and any related requirements. Risk management begins when the plant manager or employer hires the necessary staff or consultants and provides the resources for the baseline evaluations, baseline exposure monitoring, periodic remonitoring, medical monitoring, and the implementation and maintenance of controls, if necessary.

The first real step in the risk management process is the responsibility of the plant industrial hygienist: the *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 control exposures to levels less than the OEL. The industrial hygienist utilizes the resources made available by upper management and determines whether or not the risk of disease is being 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.\[f]

3.3 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 the individual workers primarily falls to the industrial hygienist[13], but will not be dealt with here.

4 CONSIDERATIONS WHEN SETTING OELS

The risk assessor, in seeking to interpret the occupational epidemiology, must address several issues when establishing an OEL. Three are considered here:

- Extrapolating from cohort to individual
- Selecting a level of 'significant risk'
- Controlling lifetime risk with single-shift exposure measurements.

4.1 Extrapolating from cohort to the individual

In those studies where historical exposure data are available the occupational epidemiologist almost always constructs job-exposure matrices in order 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 exposure 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 can 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 this hypothetical group will experience a higher risk and others a lower risk.[14,15] The range of these differences will reflect the lack of knowledge regarding such factors as individual sensitivity and the fact that the estimates of exposure are usually crude, 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 several reasons. First, 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 their working life.[16,17] This requires that risk managers at the corporate and plant level 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 as there will be individuals within the group that will experience, on average, greater exposures.[14] In summary, the risk of disease should be properly managed for *each* employee. Second, 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 the users of the chemical products that they produce.[7] So again, it is necessary to set an OEL that is considered protective for each exposed individual and not just some larger exposed population.

4.2 Selecting a level of *significant risk*

The concept of 'significant risk' has received a great deal of attention for carcinogenic agents. OSHA now utilizes the 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.\[g] OSHA recently requested guidance in defining "significant risk" for non-carcinogenic disease endpoints.[18] NIOSH[9] referred to the 1-in-1000 significant risk concept when recommending an exposure limit for respirable coal mine dust, a non-carcinogen that can produce an irreversible disease.

The ACGIH has no stated policy regarding 'significant risk'. The TLVs are set at values that are "believed" to be protective of "nearly all workers". Many TLVs are set based on 'no observed effect' concentrations reported in the literature or at levels where the risk does not significantly exceed that seen in unexposed workers. Few, if any, TLVs are set using a

f. Some industrial hygienists feel that they should not be classified as risk managers, but instead are 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 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.

g. 'Acceptable risk' or *'de minimis'* risk for occupational risk factors has yet to be quantified.

rigorous risk assessment process where the goal is to reduce risk to the 1-in-1000 goal established during the OSHA benzene deliberations.[19] (This is not to say that the ACGIH TLVs are not valid as they are often modified to reflect the current health effects literature resulting in recommended control values more stringent that those of OSHA or NIOSH.)

4.3 Controlling lifetime risk with single-shift TWA measurements

For purposes of risk assessment it is desirable to estimate long-term cumulative or average exposures.\[h] When it comes to risk management it is usually not feasible to estimate the long-term average exposure of each employee.[20] The practice that has evolved is to set a single shift OEL equal to the long-term average exposure that *appears* to be acceptable or suitably protective, based upon exposure-response analyses. This practice recognizes (a) the need to devise OELs that can be used for purposes of day-to-day risk management, (b) the need to control the long-term, working lifetime exposure of *each* individual worker to protective levels, and (c) the philosophical requirement that each OEL embody a safety factor.

Consequently, a 'controlled' work environment is one where exposures rarely or infrequently exceed the OEL, if at all. 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 regarding the revision of the benzene PEL, OSHA considered proposals for defining the PEL as either a five shift, 40-hour average or a long-term mean, calculated from *n* measurements collected over some defined period of time.[4] OSHA rejected these proposals as difficult to implement by both 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 would individual workers be adequately protected. The NIOSH RELs are based on this philosophy and, as I discuss later, it appears that the ACGIH TWA TLVs are also consistent with this philosophy.

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, when 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.

5 USING OELs 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, or as some prefer, occupational exposure management, has long been recognized as basically a 'quality control' or 'statistical process control' problem.[15,21,22,23,24,25] That is, the OEL, in statistical process control terminology, is an "upper specification limit" or "upper control limit". Consequently, the objective of an *effective* exposure monitoring program is to periodically 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'.\[i] 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.[4,15,22,23,27,28] The reader should also note that exposure monitoring is a long-term responsibility that does not end until the substance in question is no longer used.[27] Processes change, controls deteriorate, and new workers are introduced, so there is always a need for resampling and internal audits.[23,54]

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 (the 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 where exposures rarely or infrequently exceed the OEL. Such a goal does not loose 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 that is well below the TWA OEL.[4,26,27]

The primary goal of any exposure assessment strategy should be to determine if the work environment is acceptable for *each* exposed worker. A secondary goal is often to determine if the work environment is *in compliance* with the minimum

h. Peak exposures or sustained periods of high exposures may be important in the etiology of many chronic disease agents. However, exposure histories are nearly always incomplete. Consequently, the epidemiologist by default utilizes the estimates of long-term exposure in exposure-response analyses.

i. An 'observation period' or "sample period"[38] is some arbitrary, but manageable period of time, typically no more than a year[27,38]. Longer observation intervals are justified only where exposures have been demonstrated to be 'minimal' (i.e., only infrequently exceed a tenth of the TWA OEL)[23] and the processes that generate and control exposures are reasonably stable. The frequency of periodic monitoring, for work environments that are nominally *in-compliance*, will vary, depending upon 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).[23,27,38,39] 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, then the employer may be justified in reducing the number of measurements collected and/or the frequency of sampling (to, say, once every two or three years, depending on the circumstances).

requirements of a Federal or state OEL.[j] Three basic approaches have evolved for determining the acceptability of a work environment:

- individual-based exposure assessment strategies [k]
- maximum risk employee-based exposure assessment strategies
- group-based exposure assessment strategies

5.1 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 of time or during consecutive shifts) or across several months. The industrial hygienist then estimates various exposure parameters; for example: the arithmetic mean and geometric mean, the 95th percentile exposure (and the 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, then one can state that it appears that the distribution of exposures is being suitably controlled for the individual employee. If the upper tolerance limit is less than the OEL one can state, with 95% confidence, that exposures are being controlled. However, a strategy of regularly monitoring all exposed employees is, for practical reasons, not often implemented. For some occupations or work environments, where there are only a few workers and exposures range from significant [l] to poorly controlled, it is entirely feasible and necessary to periodically monitor 100% of the workers.

5.2 Maximum risk employee-based exposure assessment strategies

NIOSH and OSHA recognized early in the 1970s that there was a 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".[28] NIOSH devised an exposure assessment strategy designed around (a) the selection of the "maximum risk employee" (MRE), or the "employee [per exposure group] presumed to have the highest exposure risk", and (b) the collection of one or a few exposure measurements. NIOSH reasoned that if the exposures of the MRE are judged acceptable, based upon the NIOSH decision logic [m], then it is logical to assume that the *each individual worker* in the exposure group represented by the MRE is adequately protected. Consequently, while 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.

This strategy was recognized to have weaknesses[28,29,30,31], the primary one being that this strategy has poor power when it comes to detecting truly unacceptable work environments[29]. However, it is beyond certain that 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 into numerous 6(b) standards [n], but recognized that this strategy represented a "token" commitment that will not accurately classify all work environments.[32] The ability of industrial hygienists to reliably select one or more MREs from an exposure group has also been questioned by several researchers. Nonetheless, for initial evaluations or where resources are limited or resampling intervals are broad, the MRE concept is both recommended and commonly used by practicing industrial hygienists as a means of efficiently determining the acceptability of the work environment for the members of an exposure group.[28,33,34,35,49,61]

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j. 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 (epidemiological) purposes[20,33,81,86].

k. 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, 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*.

l. 'Significant' exposures are usually interpreted to be those above a tenth of the OEL.[23,34,49]

m. The decision logic was simple: If the first measurement is less than half the PEL, then conclude that the work environment is *acceptable* for the exposure group represented by the MRE. If the first measurement is above the PEL, then 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).

n. 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 then the "representative employee" can be considered equivalent to NIOSH's concept of the "maximum risk employee".[4,32] 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.[32]

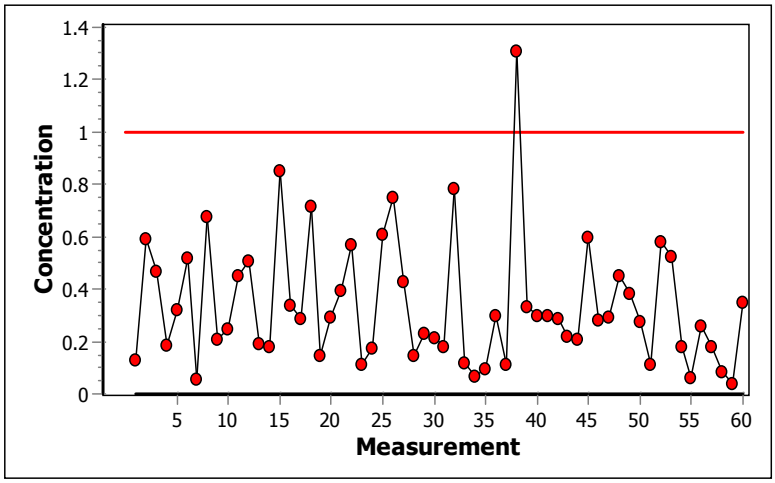

Figure 1: Simulated time series of 8-hour TWA exposures depicting a 'controlled' work environment. Single shift excursions above the TWA OEL of 1 are 'infrequent' and the long-term mean is approximately 1/3(TWA OEL).

5.3 Group-based exposure assessment strategies

Corn and Esmen[36] described an exposure assessment strategy based on the concept of an exposure group or, as they expressed 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. This *phi* (basically a Z-value) permits one to estimate the fraction of employees expected to have exposures in excess of the OEL.[36,37] If the expected number is one or greater "a hygienic problem exists"[36] 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 felt to characterize the work performed by each group member and therefore can be extrapolated to all members of the exposure group, measured or not.

Strategies similar to the Corn/Esmen strategy have been described by others.[23,27,38,39] Roach[23] described a "health risk surveillance" strategy where the exposures for a reasonably homogeneous "job-exposure group" are acceptable if they are "consistently below one-third the exposure limit". Still and Wells[38] 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 upper tolerance limit), which would then be compared to the TWA OEL. The AIHA Exposure Assessment Strategies Committee[27] added the "homogeneous exposure group" (HEG) concept. A HEG is an exposure group where 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 six to ten workers per HEG and collect six to ten measurements over a relatively short period of time. The industrial hygienist then analyzes the data and decides, using a combination of "statistical analysis and professional judgment", whether or not the "exposures demonstrate an acceptable work environment".\[o] 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 using upper tolerance limits). After the baseline data is 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 or not any 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)[40] is also based on the HEG concept. The 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.\[p] This standard contains simple decision rules for classifying *each* exposure measurement collected from an HEG. However, if six or more measurements are randomly collected then one can use statistics to estimate the probability of over-exposure for individuals within the HEG. The CEN suggests that if this probability is less than 0.1% and the work environment is reasonably stable, then exposure monitoring can be reduced or eliminated until a significant change occurs. If this probability exceeds 5%, then corrective action should take place. Otherwise, periodic monitoring should be used to confirm that the point estimate of the probability of over-exposure remains less than 5%.

These strategies are obviously best suited to exposure groups that are reasonably homogeneous; that is, there are

o. The Committee allows that the industrial hygienist may select the "most exposed worker" when determining whether or not an HEG is in compliance with a government standard.

p. "... if 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."[40]

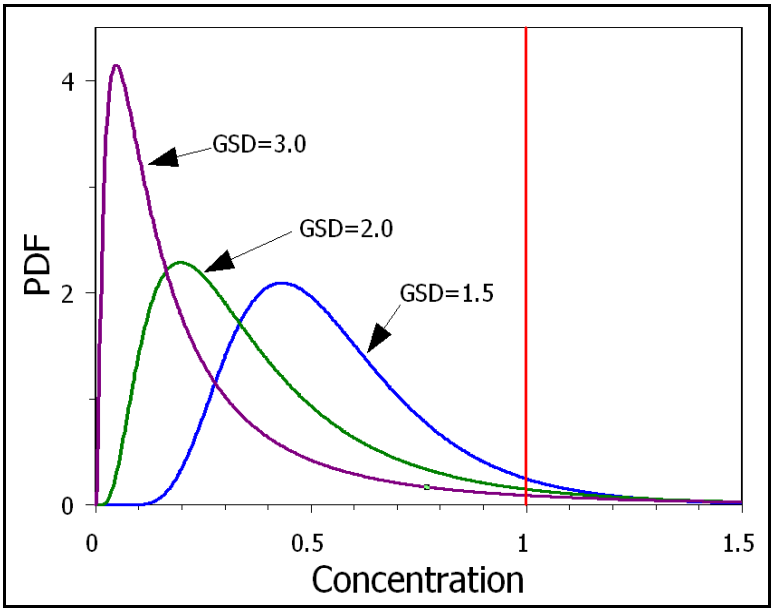

Figure 2:"Indirect control" model. Hypothetical single shift limit, or OEL, is set at 1. The exceedance fraction is fixed at 0.05 for each distribution.

GSD	GM	Mean	%>OEL	%>OEL′	%>1.5xOEL	%>2xOEL
1.5	0.51	0.56	5%	2.3%	0.4%	<0.1%
2.0	0.32	0.41	5%	3.2%	1.3%	0.4%
3.0	0.16	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′=1(1+1.645·CV_T)=1.16.)

only minor systematic differences between the individual exposure distributions of the group members. If the exposure group is heterogeneous and there are large systematic differences between individuals, then such a strategy may miss group members that are routinely over-exposed.[40] 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[41,42]. Consequently, this assumption may not be valid without an analysis of objective data.\[q]

Note that the overall goal remains the assessment of the exposures for the individual worker, albeit in an 'indirect' fashion. The assumption is made, for the sake of efficiency\[r], 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.[27,34,36,38] This assumption is valid to the extent that the exposure group is reasonably homogeneous.

6 MODELS OF COMPLIANCE FOR CHRONIC DISEASE AGENTS

What does it mean to be 'in compliance' with a TWA OEL? This 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.

6.1 Between-shift control models

Figure 1 illustrates the between-shift variation one would expect for a minimally 'controlled' work environment for an individual worker: over-exposures are infrequent and the long-term mean is a fraction of the TWA OEL. There are basically two between-shift 'control models': the 'indirect control' model and the 'direct' control model. The commonly applied 'indirect control' model holds that the distribution of exposures for an individual worker is *controlled* when over-exposures occur infrequently. Several authors and authoritative sources recommend that the 'exceedance fraction', or fraction of measurements

q. Such data would include repeat measurements randomly collected from a random sample of workers within each exposure group, which then could be analyzed using ANOVA techniques.

r. Efficiency here referring to the ability to come to a decision, right or wrong, with a limited number of measurements.

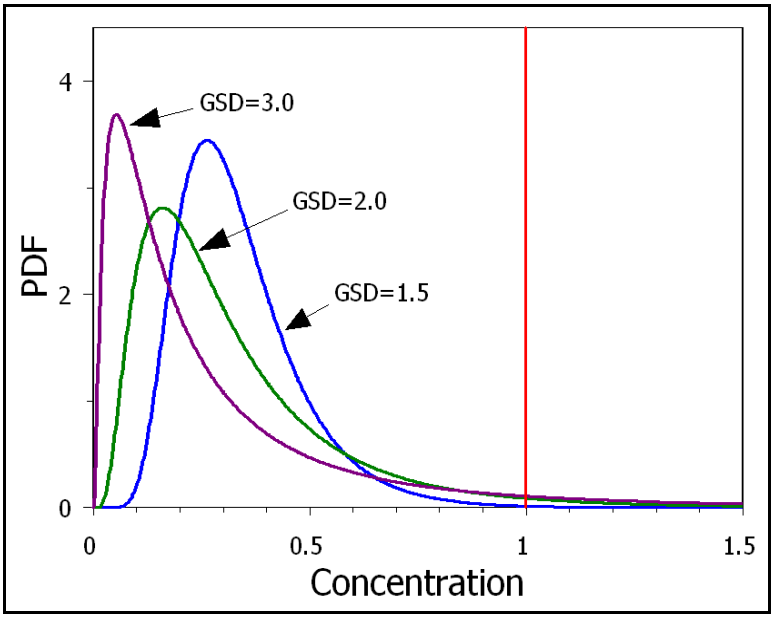

Figure 3: "Direct control" model. Hypothetical single shift limit, or OEL, is set at 1. The long-term OEL is fixed at 1/3 the single shift OEL, per the recommendation of the AIHA (Hawkins et al., 1991).

GSD	GM	Mean	%>OEL	%>OEL′	%>1.5xOEL	%>2xOEL
1.5	0.31	0.333	0.2%	<0.1%	<0.1%	<0.1
2.0	0.26	0.333	2.7%	1.6%	0.6%	0.2%
3.0	0.18	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·CV_T)=1.16.)

above the OEL, be no more than 0.05.[15,27,28,34,38,40,43] For example, NIOSH[28] stated the 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[32] indicated that a well-designed exposure sampling strategy that results in "95 percent certainty" that employees are exposed below the PEL provides "compelling evidence that the exposure limits are being achieved". While not stated with the rigor that a statistician would desire, OSHA's intent is clear: compelling evidence that compliance is routinely being achieved can be developed by a statistical analysis of exposure measurements. For example, the often used one-sided upper tolerance limit test (mentioned earlier) where one is 95% confident that 95% of the measurements are less than the OEL is consistent with NIOSH's statement above and could be considered "compelling evidence" as mentioned by OSHA.

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

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[27] suggested that a "typical LTA [i.e., long-term average exposure limit] may be one-third of an 8-hr PEL".\[s] \[t] Roach and Rappaport[44] suggested that exposures be controlled so that the long-term average exposure is one tenth or one quarter of the applicable ACGIH TLV, thus limiting the fraction of over-exposures to 0.01 to 0.05. Figure 3 shows several exposure distributions that could 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 y the AIHA[27]. Note that the exceedance fraction varies from 0.002 to 0.061, depending upon the underlying distribution.

Both models have limitations. The chief limitations of the 'indirect control' model are (a) the long-term mean exposure

s. Any LTA OEL should have a corresponding TWA OEL to prevent abuse of the LTA OEL concept. For example, it would be inappropriate to expose workers to twelve times the LTA OEL for one month followed by eleven months of zero exposure.

t. Roach[23] 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)

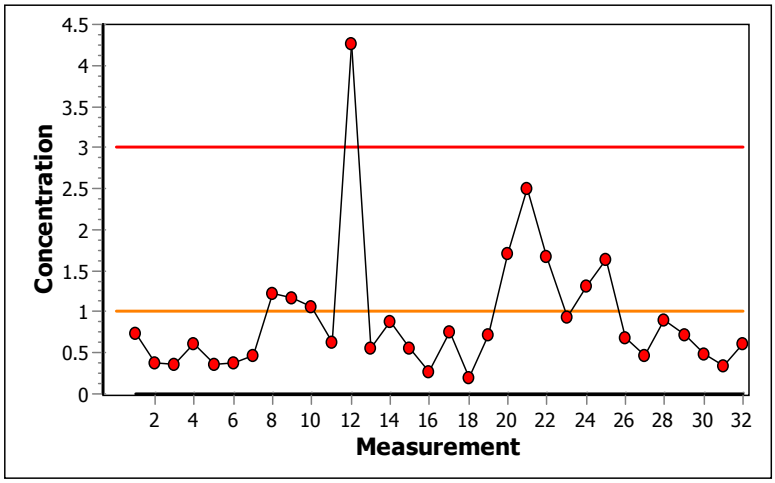

Figure 4: Simulated 15-minute short-term (average) exposures across a single 8-hour workshift where the within-shift exposures are minimally controlled (short-term excursions above 3· OEL are infrequent and the TWA OEL of 1 is not exceeded).

is controlled to different levels, depending upon the underlying GSD, and (b) 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. Since this control model is commonly used, this points to a need for risk assessors to clearly indicate 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, multi-year 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 limitations of the 'direct control' model are (a) single-shift exposures are occasionally expected to greatly exceed the TWA OEL for exposure distributions having GSDs greater than roughly 3, (b) low variability distributions might be perceived as being 'over-controlled', and (c), in general, more measurements and time are necessary to determine if exposures are controlled relative to a long-term mean standard.

In reality, it is largely academic which model is adopted for an existing TWA OEL. Convincing the many employers to practice effective risk management by any model appears to be the major problem facing regulatory agencies. Either model, *if effectively applied*, will, for the range of GSDs considered, 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.[26] Either model will also reduce the probability of a citation to less than 5% for an individual worker. For example, the captions of Figures 2 and 3 contain estimates of the fraction of exposures above the effective OEL, or the citation value\[u]. 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 control model, controls the long-term mean, single-shift excursions above the OEL, and the probability of a citation to arguably acceptable values.

A third compliance model has been advanced in recent years, but will only be mentioned for the sake of completeness. This model focuses on characterizing the distribution of individual long-term mean exposures *within* an exposure group.[45,46] The implementation of this model, as envisioned by Rappaport et al.[46], requires repeat measurements from ten or so workers, per exposure group, and utilizes 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, say 0.10 as recommended by Rappaport et al.[46]. (In principle, it is incorrect to apply this model to a TWA OEL. It is designed for determining compliance with an LTA OEL.)

6.2 Within-shift control model

The ACGIH recommends excursion limits for controlling within-shift exposures. The excursions limits and the supporting documentation readily permit the construction of a control model for the within-shift distribution of exposures. Basically, the ACGIH feels that it is possible in the majority of work environments to control within shift excursions 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 the ACGIH recommendations. Note that it does not appear that the ACGIH intends that one routinely assess and control TWA exposures using 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[47]:

> "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."

u. 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 (CV_T) for the sampling and analytical method. For a typical CV_T of 0.1 the allowance is easily calculated: SAE=(1.645· CV_T · OEL).

6.3 Interpretation of one or more over-exposures

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.\[v] Figure 5 depicts a time series of thirty six consecutive TWA measurements for a worker exposed to inorganic lead[48]. These measurements were collected as part of a research project. The single over-exposure, when compared to the 1995-96 ACGIH TLV for inorganic lead, is not likely to be a cause for great concern when considered in context with the other thirty five measurements (the average measurement was 37% of the TLV). However, assume that the measurement on day 17 was the only one available. For purposes of effective risk management, how does one interpret one or more over-exposures?

Authoritative sources recommend that *each* over-exposure be *investigated*.[23,28,33,34,35,38,40,49] The exceedance fraction calculations in the captions for Figures 2 and 3 suggest that in 'controlled' work environments random exposures above the TWA OEL and, say, 1.5 or 2 times the TWA OEL are infrequent to rare. Therefore, any over-exposure where the number of measurements is small should be a cause for concern. Also, the work of Nicas et al.[50] suggests that over-exposures should not be blamed on measurement error. Simply put, each over-exposure should be investigated.\[w] If there is compelling or convincing past exposure data\[x] to suggest that the over-exposure is most likely an anomaly, then it is reasonable to take no action beyond merely documenting the investigation. However, if no rational explanation can be found for the over-exposures, one is compelled to conclude that a systematic change of some sort *may* have occurred; after all, in a 'controlled' work environment over-exposures should be rare to infrequent (for example, see Figures 2 and 3). Follow up actions may consist of fine tuning existing controls, installation or modification of controls, or an evaluation of individual work practices. In any case, additional measurements are usually warranted in order to verify the need for additional controls or to evaluate the effectiveness of any intervention.

6.4 Criticisms and defense of OELs

The ACGIH TLVs have been criticized for not being based on a rigorous risk assessment process and being subject to industry influence.[19,44,51,52] The ACGIH[14,53] defended its policies feeling that much of the criticism was either unwarranted or unsupported and that the TLVs have long served, in the absence of better documented or more rigorously developed exposure standards, to assist occupational health professionals to assess and control exposures.

Although many of these TLVs have since been revised downwards 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[30,31,54,55] have argued that OSHA, when adopting the 1968 ACGIH TLVs, 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. A reading of Stokinger[56,57,58,59,60], Roach et al.[61], and the many other references discussing the ACGIH TLVs provides abundant evidence that TWA TLVs, and by extension the TWA PELs, were and are intended to be interpreted, for purposes of risk management, as upper limits for each TWA exposure. \[y] Practicing industrial hygienists routinely interpret the ACGIH TLVs and OSHA PELs as upper limits for the average exposure of *each* employee across *each* shift.[27,28,34,35,36.38] Furthermore, the ACGIH[62], in the preface of the 1968 TLV booklet, clearly stated:

> "Time-weighted averages permit excursions above the limit provided they are compensated by equivalent excursions below the limit **during the workday** [emphasis added]." \[z]

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v. The AIHA Exposure Assessment Strategies Committee monograph[27] 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.

w. The survey notes should be evaluated for unusual occurrences (spills, temporary control equipment breakdowns, etc.) that are unlikely to reoccur or for systematic changes in the work environment (increased production level, process changes, decreased efficiency of the control equipment, introduction of new or untrained workers, changes in work practices, etc.).

x. In the preamble to the 1987 benzene revised PEL OSHA[4] recommended that exposure data more than one year old be given little or no weight when 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" (Federal Register 57(178):42337, September 14, 1992).

y. 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.[34,61]

z. Nearly identical wording has been included in the introduction of every TLV booklet since 1968, including the current 1995-1996 booklet.

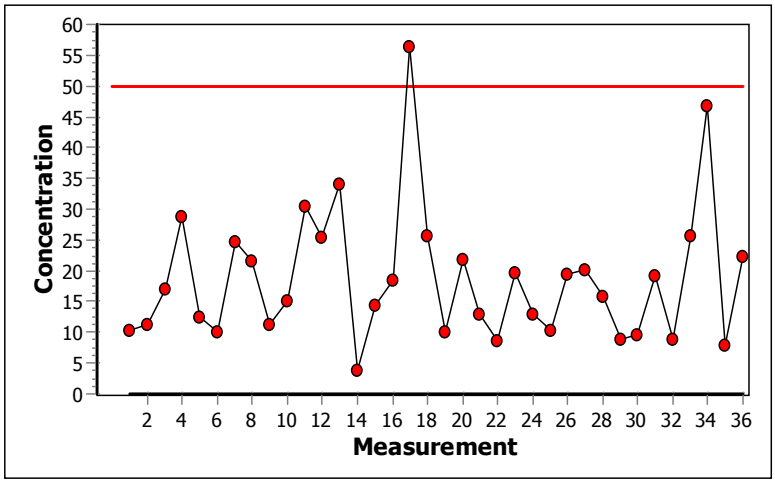

Figure 5: Consecutive measurements of airborne inorganic lead (OEL = 50 µg/m³) for "Worker A" of Cope et al.[48]

> "Enlightened industrial hygiene practice inclines toward controlling exposures to below the limit rather than maintenance at the limit."

However, this notion that 'OSHA got it wrong' continues to be discussed.[31,55]

6.5 Misinterpretation and misuse of the OEL concept

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 a TWA OEL as a long-term average (LTA) OEL.

Stokinger[56,60,63] mentioned several ways in which the ACGIH TLVs were being misinterpreted and misused. First, some were interpreting the TLVs as "fine lines between safe and dangerous concentrations".\[aa] One or a few TWA measurements that are just under the TLV does not imply that the 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 to sixteen times the TWA TLV even though the *daily* average is less than or equal to the TWA TLV. The TLV committee felt compelled, beginning in the early 1970s, to recommend specific within-shift excursion limits in order 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."[64]

Last, 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 sub-populations exist. \[bb]

Brief and Scala[65] 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

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aa. In 1969 and 1971 Stokinger lamented the fact that occasionally the "factory inspector" and "legal profession" interpreted high short-term (i.e., partial shift) measurements, 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 TLVs.

bb. 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 will vary, the site and mode of action can vary, and, most importantly, the actual risk depends upon the likelihood and severity of exposure. (It can also be assumed that the exposure-response curves for different substances will have different shapes or slopes.)

of the data base for the TLV".[66] The ACGIH[64] recommends that, among other models, the "Brief and Scala model" be used as guidance for reducing the TLV when there is a non-traditional work schedule. OSHA adopted a simpler scheme for the 1978 lead (see 29CFR1910.1025) and the 1994 cadmium PELs (see Federal Register 57:42336, 1992).

Occasionally industrial hygienists will compare the average exposure of an exposure group to a TWA OEL. This has the effect of changing the OEL's 'target' from the individual worker to the exposure group and is valid to the extent that the exposure group is reasonably homogeneous. For a group where 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 over-exposed.[15] Such a practice was considered and rejected by NIOSH[28] as a valid technique for determining compliance with legal OELs except under the extraordinary circumstance where the overall GSD for the exposure group is 1.15 or less (meaning that, for practical purposes, the exposure group is a true homogeneous exposure group).[cc]

An OEL can be 'weakened' by extending the averaging time for a single 'measurement' from a single shift to multiple shifts.[35] 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 the ACGIH TWA TLVs. Such a practice explicitly permits frequent single-shift overexposures and creates an OEL′ which will not provide the level of protection inherent in the original OEL. When issuing the 1978 final lead PEL OSHA explicitly forbade multi-shift 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."[67]

The ACGIH[64,66] 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 ...". While it is abundantly clear to most practicing industrial hygienists that the TWA TLVs are defined as limits for each TWA exposure, there is a tendency among a minority to 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, in the view of some, 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 (see the previous discussion on models of compliance), the level of protection provided by such a modified TLV cannot possibly equal the level of protection provided by the original TLV. Since 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.

7 SOURCES OF OELs

The number of chemicals found in the nation's workplaces is literally in the tens of thousands. However, OELs have been established for only 2000 or so substances.[7] 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.[7]

7.1 American Conference of Governmental Industrial Hygienists

The history of the ACGIH and the TLVs has been well described elsewhere.[56,68] The ACGIH TLV list now contains over 700 recommended exposure limits for substances ranging from simple irritants to chronic disease agents to 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 as such well served the occupational health community before the creation of OSHA, MSHA, and NIOSH. 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, or STEL.[dd] The averaging time for this limit is fifteen 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, or 8 hours. The ACGIH recommends that the TWA TLVs be reduced when workshifts are longer than 8 hours and/or the work week consists of more

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cc. 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. We instinctively recognize the flaw in this physician's reasoning and would probably soon switch to a different practice. Yet, without long experience or objective evidence that each exposure group is reasonably homogeneous, risk managers frequently apply similar reasoning to the analysis of workplace exposures.

dd. The 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.[64]

than 40 hours.

The ACGIH[64] 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 may develop an 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 this value. Which is why, for *risk management* purposes, the ACGIH[64] defines the TWA TLVs as limits for the average exposure across each 8-hour shift. Stokinger[60] 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 as to the TLV committee's intentions[69]:

> "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.[66] 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[66] 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 (a) adequately protect *individual workers* and (b) to partially account for the uncertainty in the epidemiological data. A review of the ACGIH 1991 documentation for OSHA's 6(b) substances (see footnote ff), 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\[ee] 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 epidemiological or toxicological literature. This is due to the fact that the TLV committee is not required to closely examine issues of feasibility for all affected industries or engage in lengthy cost-benefit debates. This happy state of affairs may be changing in that 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 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 felt protective for "nearly all" workers.[64] Consequently, the ACGIH does not get mired in disputes with industry regarding definitions of 'significant risk'. Others view this as a disadvantage feeling that the TLVs do not provide adequate protection for enough workers[44] or for susceptible sub-groups[70]. In summary, specific ACGIH TLVs may not be as protective as the more recent OELs of OSHA and NIOSH, but, taken as a whole, the TLVs better reflect current changes in our understanding of the relationship between exposure and occupational disease.

7.2 American Industrial Hygiene Association

The AIHA issues Workplace Environmental Exposure Level guides (WEELs) for substances for which there are no authoritative or legal OELs.[71,72] The number of WEELs on the current list is less than 100. Candidate substances are solicited from the AIHA membership or are 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".[72] 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 workweek) or as ceiling values not be exceeded during each shift.

7.3 Occupational Safety and Health Administration

OSHA[16] is permitted to "promulgate" occupational health standards. Each standard

> "...most adequately assures, 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

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ee. 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.

with by such standard for the period of his working life."

OSHA initially adopted existing consensus air quality standards and those 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, due to the frequent demands for *scientific certainty* placed on government risk assessors and to 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. While 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"[73] the PEL revision process is sufficiently difficult and time consuming that OSHA has managed to modify only eleven PELs.\[ff] Attempting to compensate for a lack of progress OSHA issued in 1989 a comprehensive air contaminants standard that modified more than 400 PELs. Because there were objections from both industry and labor a court of appeals nullified the revised PELs.[74] As a result, the vast majority of the current PELs are based on criteria that are approaching thirty years of age. OSHA[18] recently announced its intention to once again start the PEL revision process and solicited comments regarding the selection of target chemicals, appropriate risk assessment methodology for carcinogens and non-carcinogens, and the determination of *significant risk* for carcinogens and non-carcinogens. OSHA listed twenty chemicals as candidates for revision and intends to revise the PELs for twenty or so substances at a time, thus avoiding the problems encountered during the earlier PEL revision effort.

While OSHA contemplates revising the PELs Congress is considering proposals to make risk assessment at the Federal level more *rigorous*, thus presumably more *defensible*.[5] Given that it is likely that the PEL revision process will be slow at best, resulting in significant delays before more protective PELs are adopted[75], enlightened companies are likely to rely on the more current TLVs or to devise corporate OELs that utilize the latest epidemiological and toxicological results.

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 a violation of a TWA PEL defined as the upper limit for long-term or lifetime mean exposure. Similarly, if TWA PELs were defined as, say, the 95th percentile exposure, employers would no doubt be inclined to claim that any over-exposure measured during an OSHA health inspection was one of the "allowed" over-exposures.\[gg] However, since there is uncertainty in every exposure measurement, due to sampling and analytical 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 issue a citation only when the lower confidence limit exceeds the PEL.[76] If the company has historical exposure data the OSHA compliance officer is instructed 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".[76]

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

OSHA has considered and rejected as impractical industry proposals to define TWA PELs as long-term values.[4] However, OSHA noted in the preamble to the 1987 benzene standard:

> "... there is no requirement to control exposures so far below the PEL so as to ensure that 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."[4] (p.34515 of reference 4)

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 regarding the 1987 benzene standard OSHA[4] stated:

> "... virtually all employers keep long term average exposures under the PEL by a margin and where feasible under the

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ff. asbestos, vinyl chloride, inorganic arsenic, lead, benzene, coke oven emissions, cotton dust, 1,2-dibromo-3-chloropropane, acrylonitrile, ethylene oxide, and formaldehyde.

gg. 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.

hh. 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.

action level with a margin." (p.34508)

> "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)

> "... 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 stated OSHA[67] 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 no more than one in twenty single shift TWAs exceeds the PEL and assumes that exposures are lognormally distributed with characteristic GSDs in the range of 1.5 to 3, then 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 Figure 2.) Interested readers should review OSHA's well-conceived, but hardly noticed 'non-mandatory' appendix to the 1992 formaldehyde standard[32] as it provides considerable 'common-sense' guidance regarding the design and implementation of an exposure monitoring program.

It should be noted that OSHA's mandatory monitoring requirements were designed to establish *baseline* information regarding employee exposures. Only under the "best of circumstances [will] all questions regarding employee exposure be answered".[32] For example, if exposures for all employees are truly *controlled* or better, then the application of OSHA's mandatory requirements will almost certainly result in the employer *concluding* that exposures are *acceptable*. However, low exposures collected on a single day or across several days will not automatically guarantee the employer that the workplace is currently, or will continue to remain, in compliance with a TWA PEL. This is because even poorly-controlled work environments often have a majority of exposures less than the PEL. The employer should be aware that in these circumstances the strict application of the minimalistic mandatory requirements for exposure monitoring can often lead the employer to mistakenly conclude that exposures, in general, are acceptable.

7.4 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".[16] Since then NIOSH has developed and issued over 100 "criteria documents" recommending new or revised exposure limits. These limits are called Recommended Exposure Limits, or RELs. These are not legal limits, but are recommendations to OSHA and occasionally the Mine Safety and Health Administration (MSHA). With one exception, that being for 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 ...".[77]

NIOSH's criteria document on respirable coal mine dust[9] illustrates a risk assessment process that is similar to that recommended by the NRC[8]. NIOSH considered both the epidemiology, sampling and analytical feasibility, and technological 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 was 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 recommended an upper limit of 1 mg/m^3 for each single shift TWA. NIOSH[9] 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:

> "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."

> "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, the development and application of improved dust control techniques, the use of personal protective equipment as an interim measure if exposures cannot be adequately controlled, and the routine monitoring of exposures. Note that NIOSH provided sufficient information so that, in principle, either the 'indirect' or 'direct' between-shift control model could be use to develop a statistically rigorous exposure assessment strategy; that is, both the 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.

7.5 Corporate and other OELs

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.[6,7] (Industrial hygienists should review Harris[78] for a discussion of professional ethics and the use of new toxicological and epidemiological information.) Paustenbach[6] 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 toxicological and epidemiological data are not available.

Producers of specialty chemicals, byproducts, intermediate chemicals and pharmaceuticals[79] regularly set internal or corporate OELs. The process is usually a multi-disciplinary one 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.

8 A PHILOSOPHY FOR OCCUPATIONAL EXPOSURE MANAGEMENT

The 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 on 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.[80] However, when it comes to *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 primarily concerned with that patient's *current* 'exposure' to excess cholesterol. The physician has little knowledge regarding 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 ensure that during period of time that this patient is under his/her care that the risks associated with elevated cholesterol levels are properly managed, i.e., minimized. The physician does this through the use of proper and regular tests, the comparison of *each* cholesterol measurement to a target value corresponding to an acceptable level of risk, and the regular issuance of sound advice based upon the current measurement. Assuming that the patient visits the physician once per year one could say that 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 to the target value. The current high value indicates that a *change* of some sort has occurred and needs attention. \[ii]

Like the personal physician, the plant industrial hygienist is responsible for the proper management of the risk experienced by each plant employee. The industrial hygienist usually has little knowledge regarding 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 this employee after the industrial hygienist leaves or the employee moves on to other jobs or work sites. What the industrial hygienist can do, however, is act as the steward of each employee's good health by ensuring that each employee's *current* risk is properly managed during the period of time that the industrial hygienist is employed by this company and the employee is in his/her sphere of responsibility. Consequently, current exposure data (see footnote x) has the most 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 section on the interpretation of single over-exposures).

9 CURRENT TRENDS

There are several trends that have the potential to have an impact on the practice of industrial hygiene:

- Development of hybrid exposure assessment strategies
- Development of occupational exposure databases

ii. 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 in order to *balance* the excessive exposures. With the exception of coal miners (who can be transferred to low dust areas based on evidence of 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.

- Increased capability to collect exposure data
- Increased use of formal statistical tests
- Statistically defined OELs
- A generic "performance-based" exposure assessment standard.

It has long been recognized that data collected solely for the purpose of determining compliance usually reflects the exposures of the maximum risk employees within each exposure group. Such data can 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.[20,27,81] Since 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.[82,83] Such databases could be used to generate research hypotheses, evaluate the efficacy of different types of controls, and provide accurate industry-wide 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.*

There were several trends during the 1960s that led to this model: (a) the movement from area to personal exposure measurements and (b) the move from short-term (i.e., less than 30 minutes) to full-shift (or nearly full-shift) sampling[34]. These trends were primarily the result of the development of battery-powered personal sampling pumps. For particulate substances the development of sensitive analytical balances and improved filtration materials permitted industrial hygienists to shift from measuring 'particles per unit volume' to 'particulate mass per unit volume'. During the 1970s a concern on the part of NIOSH and OSHA was to ensure that *reasonably* accurate sampling and analytical 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 analytical methods with coefficients of variation less than 0.1. However, even imperfect or imprecise measures of exposure, such as we have with asbestos, 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, analytical method sensitivity, and in the development of automated analytical 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.[84] The increased use of direct reading instruments coupled to data storage devices, the development of electronic sensors for specific chemicals, and the increased availability of passive dosimeters provides industrial hygienists the means to better characterize exposures for a larger percentage of the workforce and may eventually lead to the inexpensive and accurate characterization of the within-shift and between-shift exposure profiles for nearly all workers.[85]

In the 1960s and well into the 1970s data analysis often consisted of the comparison of one or several TWA estimates to the TWA OEL.[28,34,57,59, 61] Consequently, formal statistical tests were used in a compliance context to determine if 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 (for example, see footnote m).[28] As the quantity of data increased industrial hygienists have adopted ever more sophisticated and statistically defensible data analysis procedures[27,31,33,34,40,49,86], although the need for simple decision rules remains[33,35,38,40].

The AIHA[87] recently issued a 'white paper' on generic exposure assessment standards and recommended that OSHA issue "clear statistical definitions of over-exposure". 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 latter direction in a criteria document on 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.[9] It would be helpful if regulatory agencies and authoritative bodies would clearly state both the 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[88] 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 regarding 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[87,89] \[jj]

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jj. 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.[32]

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