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Industrial Hygiene Exposure Assessment—Data Collection and Management

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Exposure to toxic materials always entails some level of risk. This risk reflects both the inherent toxicity of a substance and the frequency, duration, and severity of exposure. Risk management refers to the process of assessing and, if necessary, reducing exposure and therefore risk for exposed individuals. An exposure assessment is an essential component of risk management for determining a course of action. The actual measurement of current exposures to gases, vapors, or particulates may not be required, as there are qualitative and semiquantitative exposure assessments. It is often the case, however, that measurements are necessary for initial or baseline evaluations. Furthermore, periodic sampling and occasional audits are necessary for validating earlier assessments and for evaluating exposure trends in the work environment. Consequently, an industrial hygienist is often faced with questions regarding the collection, analysis, interpretation, and management of occupational exposure data.

The purpose of this chapter is to suggest appropriate questions and provide reasonable answers regarding the *collection* and *management* of occupational exposure data. Chapter 16 (Hewett[1]) covers data *analysis* and *interpretation*. Both chapters presume some familiarity with exposure limits and exposure-measuring instrumentation. Furthermore, quantitative exposure assessment is only one component of a "comprehensive exposure assessment" program.[2,3] Readers should consult the reading list at the end of this chapter for more information regarding comprehensive exposure-assessment programs and broader discussions regarding industrial hygiene, instrumentation, and statistics.

An additional purpose of this chapter is to provide guidance for developing what could be called a philosophy for occupational exposure management. Because exposure-monitoring programs must be designed and tailored for a wide variety of work environments, it is critical that we first adopt reasonably consistent interpretations of the occupational exposure limits and agree on the goal of an effective exposure-monitoring program.

Occupational Exposure Management

Occupational exposure management refers to risk management in the workplace; that is, the process of assessing and controlling risks associated with exposure to toxic chemicals, physical agents (e.g., radiation, heat, noise, vibration), biological agents (e.g., bacteria, fungal spores, and other biologic aerosols), and ergonomic hazards. Exposure management incorporates the traditional industrial hygiene functions of *hazard recognition*, *hazard evaluation*, and *hazard control* (Table 15.1) and requires the coordinated activities of plant management, medical professionals, toxicologists, control technology and process engineers, and safety professionals. However, many of the responsibilities of exposure management are assigned to an industrial hygienist; that is, a professional "qualified by education, training, and experience to anticipate, recognize, evaluate, and develop controls for occupational health risks."[4] The end result of effective exposure management is an adequately controlled "exposure profile"—or distribution of exposures—for each employee.

Hazard Recognition

Hazard recognition is the first step in the process of exposure (risk) management. In principle, it consists of a three-part basic characterization: (a) characterize or describe the work environment; (b) assemble information regarding toxicology and applicable OELs; and (c) define initial or tentative exposure groups. However, exposure management may proceed from the identification of a single, predominant toxic substance, followed by the identification of all exposed employees. Or it might begin by first grouping workers by similarity of process, job or task, area, and controls, and then proceeding to a comprehensive assessment of the work environment, which includes an inventory of all potentially toxic substances, for each exposure group.

TABLE 15.1 Occupational Exposure Management = Risk Management

Risk Management Step	Risk Management Action
Hazard recognition	Characterize or describe the work environment for each group
	Assemble information on toxicology and applicable OELs
	Define initial or tentative exposure groups*
Hazard evaluation	Collect/model exposure data, then . . .
	Analyze exposure data, then . . .
	Interpret exposure data
	Manage the exposure database
Hazard control	Substitute less toxic/hazardous materials, and/or . . .
	Enclose process or worker, and/or . . .
	Install/modify general or local ventilation, and/or . . .
	Modify work practices, and/or . . .
	Implement administrative controls,** and/or . . .
	Require interim personal protective equipment

*The exposure group definitions and potential for new or additional exposures should be reassessed any time there are significant changes in the process, production rate, ventilation controls, assigned tasks, or work practices or when new workers are introduced.
**Many OSHA 6(b) standards forbid the rotation of workers through high-exposure areas.

Workplace Characterization

A basic characterization or description of the workplace is needed for each exposure group.[2,5,6] This characterization should be documented and include (a) a description of the workplace; (b) a description and review of the production processes, work patterns, emission sources, and existing controls (engineering, administrative, and personal protective); (c) a list of the job descriptions and the tasks associated with each job; (d) an inventory of the chemical, physical, biological, and ergonomic hazards associated with each job or task; (e) the number of workers per shift, by job title, and an evaluation of any real or potential differences between shifts; and (f) shift length and recovery time information (necessary for adjusting exposure limits for nontraditional work shifts, discussed below).

Toxicology

Information on health effects can be obtained from material safety data sheets, chemical suppliers, standard references on occupational toxicology, trade or professional organizations, and federal agencies such as OSHA and NIOSH. Applicable federal, authoritative, or corporate OELs should be identified and the relevant OEL documentation reviewed to determine the reasons and rationale for setting the OEL. For example, one should consult the ACGIH TLV documentation when using any ACGIH TLV, or the Federal Register preamble for each OSHA 6(b) Permissible Exposure Limit (PEL).*

Exposure Groups

Exposure groups have gone by several names: "homogeneous risk group,"[7] "exposure zone,"[8] "homogeneous exposure group,"[5,6] "uniform exposure group,"[9,10] and "similar exposure group,"[2] among other terms. In this chapter the term "exposure group" will be used to refer to any logical grouping, based on either observation or any objective methodology, that is expected to result in a reasonable degree of homogeneity with respect to the conditions of exposure (e.g., similarity of process, toxic substance, jobs/tasks, and controls). It is possible for an exposure group to consist of a single employee who is engaged in unique or distinctly different activities.

While the "exposure group" will be our basic unit for aggregating workers, it must be recognized that we are not interested in controlling the average risk in each exposure group; we are interested in controlling the risk for each and every member of the exposure group. The exposure group concept is used simply because most employers lack the resources to routinely monitor the exposures of *each* employee.

Ideally, all exposure groups should be perfectly homogeneous; that is, workers within each exposure group should perform identical tasks using identical work practices and be subject to identical controls for identical periods of time. If this were so, measurements collected from any worker could be used to evaluate the exposure profiles of all workers within the group. However, in reality all exposure groups are heterogeneous with respect to the above factors, but to a greater or lesser degree, depending on the inherent exposure variability for a particular work environment and workforce, and the skills and experience of the industrial hygienist when establishing initial exposure groups.

*OSHA 6(b) PELs are those that have been promulgated since 1970. These are more *complete* standards than the Table Z1, Z2, and Z3 standards in the sense that they include specific requirements for explosure monitoring, medical surveillance, hierarchy of controls, use of personal protective equipment, and so on. These additional requirements, when implemented, further reduce or manage risk. The *Federal Register* preamble justifying a 6(b) PEL should be reviewed. The complete text for many 6(b) PELs can be found on the OSHA Internet home page.

Hazard Evaluation

Once suitable and sufficient background information has been assembled it is necessary to determine if the substance in question represents a *hazard* to the employees, given the conditions of use and the frequency, duration, and severity of exposure. This hazard evaluation, or exposure assessment, comes in three varieties: qualitative, semiquantitative, and quantitative. A quantitative exposure assessment refers to the collection of current exposure measurements and is warranted whenever information regarding exposures is missing or uncertain. Qualitative and semiquantitative exposure assessments are used to determine the need for a quantitative exposure assessment by addressing the question: "Are significant exposures likely to occur under the expected conditions of use?"[11]

A qualitative assessment might involve the determination that the substance in question is present in insignificant quantities or that the operation or process is totally enclosed with an extremely low probability of inadvertent release, even during maintenance activities.* For example, according to the OSHA benzene standard[12] products containing less than 0.1% of benzene are exempt from regulation.

A semiquantitative exposure assessment utilizes "objective" exposure data. For example, in the OSHA cadmium standard, objective data are defined as "information demonstrating that a particular product or material containing cadmium or a specific process, operation, or activity involving cadmium cannot release dust or fumes in concentrations at or above the action level [i.e., half of the Time-Weighted Average (TWA) PEL] even under the worst-case release conditions."[13] Objective data may consist of historical exposure data (previous data from the same work environment and usually not more than one year old), analogous exposure data (data from similar processes or operations), or predictions from exposure modeling[2] (statistical models or physical/chemical models). Any of these exposure assessments, but particularly quantitative exposure assessments, can be divided into four stages: data collection, analysis, interpretation, and management.

Data Collection

A sampling strategy should be devised before actual data collection begins. The sampling strategy indicates the type of survey (baseline survey, surveillance, audit, or other) and the procedure for selecting workers to be monitored.

*Routine and periodic maintenance activities often result in high exposures.

Data Analysis

If sufficient data are collected during a baseline evaluation or subsequent reevaluations, then summary statistics and compliance statistics can be calculated. The data should first be evaluated to determine if the lognormal distribution assumption applies. Generally six or more measurements are required before stable statistics can be calculated.[2,5] Data analysis procedures are presented in Chapter 16.

Data Interpretation

A written "decision logic" is necessary for determining if a particular set of exposure data indicates that the work environment is "acceptable" or "unacceptable," or if more information/data are needed. A decision logic may consist of simple decision rules or a formal statistical test. Decision rules are useful when only a limited number of measurements are available. Formal statistical tests are usually applied when sufficient data are available, usually six or more measurements. Either way, the goal is to determine whether or not the "exposure profile" for each employee in the exposure group is acceptable. Data interpretation procedures are presented in Chapter 16.

Data Management

Although mentioned last, the identification of the relevant descriptors of exposure data and the development of a data management system should come early in the hazard evaluation process. There are many potential users of and uses for exposure data.[14,15] Exposure data may be used for determining compliance with existing federal regulations, for assessing the status of existing exposure controls, and later for estimating cumulative exposures in an epidemiological study. The data may used in the future by researchers or the designers of other facilities. There is growing concern that industrial hygienists collect and safeguard for future use not only the exposure measurements, but also comprehensive descriptive information regarding the work environment and workforce. The resulting "occupational exposure databases" could then be used to evaluate the efficacy of different types of controls and provide accurate industrywide exposure data for trade organizations and standards-setting organizations.

Hazard Control

Once it is determined that the exposure profile for an individual worker or exposure group is unacceptable, steps must be taken to reduce exposures. A written "haz-

ard control" plan should be developed, maintained, and continuously updated. If feasible, exposures should be reduced through substitution of less toxic substances, engineering controls (e.g., process enclosure, and local and general ventilation), work practice modification, or, as a last resort, through the use of personal protective devices. Often all that is required is the fine tuning or modification of existing controls. The evaluation of individual work practices and analysis of the task components of a job often leads to ways of substantially reducing exposure. 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. Burton[16] provides excellent overviews of the topic of hazard control.

Comments

Exposure Management Is a Long-Term Responsibility

Exposure management does not end until the substance in question is no longer used. Processes change, controls deteriorate, and new workers are introduced, so there is always a need for periodic reassessments, resampling, and internal audits. Every exposure management program should incorporate a "continuous improvement" concept.[2,17,18] For example, after initial or baseline exposure assessments where the focus is on exposure groups, industrial hygienists then focus on evaluating and controlling exposures during individual tasks. The expectation is that by periodically auditing, evaluating, and controlling task-based exposures, along with periodic evaluations of full-shift exposures, exposure groups tend to become more homogeneous and exposures in general tend to decline. Furthermore, as reviewed by Hewett,[19] most authorities recommend that every overexposure be evaluated to determine if the work environment has deteriorated.

Documentation of the Absence of Exposure

Because employees and local communities are increasingly concerned with emissions of presumptively toxic materials both within a facility and into the general environment, it is often important to accurately document the *absence* of exposure, or the fact that exposures are *minimal*.[2] For such data to be convincing for risk-communication purposes, they must be collected using a thoughtfully designed exposure-monitoring program, similar to those designed for employees known to be significantly exposed.

Biological Monitoring

For many substances Biological Exposure Indices (BEIs) have been developed.[20] These provide an additional means for assessing worker exposure. The documentation for each BEI should be consulted for guidance regarding the comparison and interpretation of biological measurements.[21]

Dermal Absorption

For numerous substances, principally organic and organo-metallic chemicals, skin contact and absorption represents an important route of exposure. Many of the substances in the ACGIH TLV booklet[20] have a "skin" designation indicating that skin absorption can be significant. Because significant skin contact can invalidate a favorable assessment of airborne exposure, the potential for skin contact should be evaluated, along with the potential for exposure by inhalation. (See Ref. 2 for an introduction to assessing exposure by dermal absorption.)

The Role of Judgment and Experience

Because the number of exposure measurements is often too small to permit conclusive determinations, and most work environments are rarely stable (i.e., exposures change due to season changes, controls becoming less effective, and production-level changes), there is always a role for experience and judgment when exposure measurements are interpreted. There is no substitute for a sound knowledge of the process and good observational skills. The employer or representative should correlate observations of employee work practices and knowledge of the process parameters (production rate, substance, rate of use, ventilation) with exposure measurements.

The periodic classification of each work environment as acceptable or unacceptable requires numerous judgments. Judgment is important for defining initial and revised exposure-group definitions, for determining when to resample, for ranking and prioritizing exposure groups for evaluation, for determining if an operation is reasonably stable or dynamic and subject to change, and so on. The accuracy of these judgments can be expected to improve as one gains experience relating actual measurements with observations. The collection and analysis of exposure data should be used to verify or validate one's judgment, or when one is simply uncertain regarding the magnitude of exposures.[2]

There will always be uncertainty in the estimation of an exposure profile for an individual or exposure group, particularly if historical or surrogate exposure data are used. The confidence interval calculations described in

Hewett[1] (Chapter 16) can be used to quantify the uncertainty regarding our estimates of the parameters of this exposure profile. Furthermore, there will always be uncertainty in the level of protection offered by any OEL.[2] For example, legal OELs are often dated and more protective OELs have since been recommended by other organizations. Or an internal or corporate OEL may be based on "no observed adverse effect" data and the level of long-term risk is simply unknown. In these and similar instances one is advised to be conservative (i.e., tend towards overprotection) when interpreting exposure data or adopt an interim or working OEL that is a fraction of the legal OEL.[2]

Occupational Exposure Limits (OELs)

In order to design an ethical and defensible exposure-monitoring program it is necessary to assign a statistical interpretation to an occupational exposure limit (or OEL). In this chapter the various types of OELs are assigned statistical *interpretations*. Each interpretation is designed to be consistent with the *definition* assigned to the OEL by the sponsoring organization (e.g., Occupational Safety and Health Administration [OSHA], American Conference of Governmental Industrial Hygienists [ACGIH], and National Institute for Occupational Safety and Health [NIOSH]). Other interpretations are possible. However, as noted by Roach[22] in 1967, "[it] is important that hygienic standards should not be given widely different interpretations."

Unless less toxic substitutes can be found or processes totally enclosed, an OEL is needed for determining whether a work environment is currently acceptable or unacceptable.[2,5,23] A workplace is judged to be acceptable if the exposure profile for each employee is sufficiently controlled.

Components of an OEL

OELs can be thought of as "legal," "authoritative," "internal," or "working." Legal, or regulatory, OELs are those set and enforced by state or federal agencies, such as OSHA and MSHA. Authoritative OELs are recommended by organizations such as the ACGIH and AIHA, and federal agencies such as NIOSH. Companies often devise internal, or corporate, OELs for substances for which there are no legal or authoritative OELs,[23] or when the legal or authoritative OEL is dated. In the absence of a legal, authoritative, or corporate OEL, the industrial hygienist should devise a working or provisional OEL, to be used until a corporate or other OEL becomes available.[2,23]

Each OEL consists of three components: (1) a concentration, (2) an averaging time, and (3) a target.[19] (Legal OELs often include additional requirements for exposure monitoring, medical monitoring, respiratory protection, and/or exposure controls.) The "concentration" refers to the obvious numerical value and units of the OEL. The "averaging time" refers to the period for which an average exposure is estimated. The appropriate averaging time is set by the originator of the OEL (e.g., OSHA, ACGIH, NIOSH).

Ideally, the target (or focus) of all legal and most authoritative OELs is the *individual worker*. Our goal is to protect *each* individual worker. However, due to limited resources we often focus on exposure groups rather than individuals. Consequently, our *conclusions* regarding the exposure group must be reasonably *predictive* of the exposures experienced by each member of the group.

An OEL of some sort is necessary for the evaluation of data. Since only a relative handful of the tens of thousands of substances and mixtures encountered in industrial operations have OELs, many corporations find themselves compelled by both ethical and liability considerations to develop corporate occupational exposure limits. According to Paustenbach[23] companies should accept three propositions: (1) OELs—legal, authoritative, internal, or working 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) corporate or provisional OELs should be set even if adequate toxicological and epidemiological data are not available. Once a corporate or provisional OEL is set by the corporate risk assessors, the plant risk manager or industrial hygienist should treat it like any legal or authoritative OEL.

Exposure Measurements and Exposure Profiles

The term "exposure measurement" refers to a single estimate of the average exposure across the averaging time specified by the OEL. For example, a typical exposure measurement is an estimate of the average exposure across a single shift. Such a measurement would be compared to a TWA OEL. However, often the full-shift measurement is itself calculated using several partial-shift measurements. Calculation procedures for estimating full-shift, time-weighted average (TWA) exposures can be found in nearly any industrial hygiene reference and the ACGIH TLV booklet.[20]

Though not often done, it is technically possible to measure the full-shift TWA exposure of a single worker for each of the approximately 250 working days per

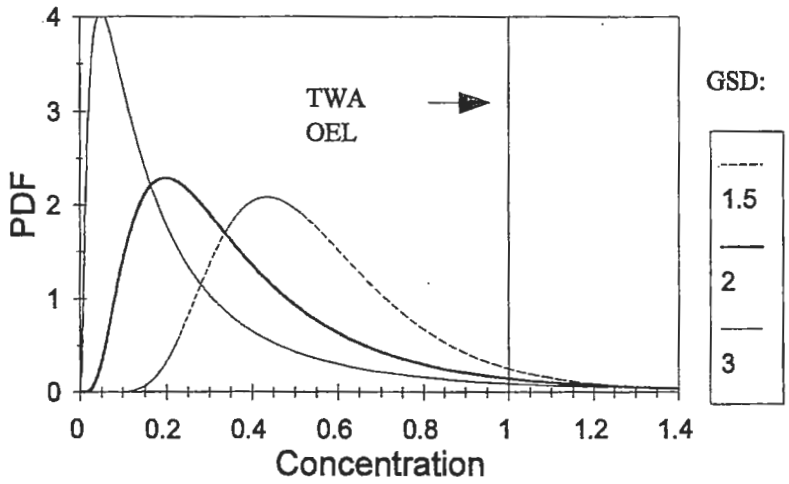

FIGURE 15.1 "Indirect control" model. Hypothetical single-shift limit, or TWA OEL, is set at 1. The exceedance fraction is fixed at 0.05 for each distribution. (PDF = probability density function.)

GSD	*Mean*	*% > OEL*
1.5	0.56	5 %
2.0	0.41	5 %
3.0	0.30	5 %

year. These measurements could then be plotted in a histogram, the shape of which would be an estimate of the true exposure distribution for that worker during that year. The term "exposure profile"[2,5] is used to refer to this distribution. Most industrial hygienists find that the lognormal distribution is an adequate model for describing such exposure profiles and for predicting future exposures.[10] As depicted in Figures 15.1 and 15.2, lognormal distributions tend to be skewed, with more measurements toward the low end and a long tail extending toward the higher exposures.

The exposure profile of an exposure group is a composite of the individual exposure profiles of group members. The lognormal distribution can often be used to describe this exposure profile as well.

Acceptable Exposure Profiles

Because exposures derive from continuous distributions with a zero lower boundary and a nearly unlimited upper boundary, there will always be some finite probability that a random exposure will exceed the applicable OEL. An "acceptable" exposure profile is usually one where such "over-exposures" occur infrequently. However, there are few OELs where an acceptable exposure profile has been defined in rigorous statistical terms. Therefore it is necessary to assign a practical, or working, *statistical interpretation* to each OEL. Table 15.2 contains statistical interpretations as recommended by several organizations or authorities. Starting with these definitions, we can then proceed to define both acceptable and unacceptable exposure profiles.

The exposure parameter most often mentioned in the industrial hygiene literature for rating the acceptability of an exposure profile is the 95th percentile exposure. There is general agreement that an exposure profile is "acceptable" if the *true* 95th percentile is equal to or less than the OEL.[2,7,8] A variation on this theme is to calculate the fraction of overexposures, or exceedance fraction.* If the true exceedance fraction is less than or equal to 5%, then the 95th percentile exposure is also less than or equal to the OEL. Exposure profiles considered "acceptable" according to this exposure control model are depicted in Figure 15.1

Rapid acting substances are typically assigned ceiling limits. These OELs are designed to limit exposures as measured over a few seconds (e.g., when measured with a direct reading instrument) to a few minutes. The ACGIH defines a TLV-Ceiling as a value that "should not

*The exceedance fraction relates to a specific OEL, whereas the 95th percentile can be compared to any OEL. Consequently, the 95th percentile is a more useful statistic where there are several applicable OELs (such as an OSHA PEL, NIOSH REL, and ACGIH TLV).

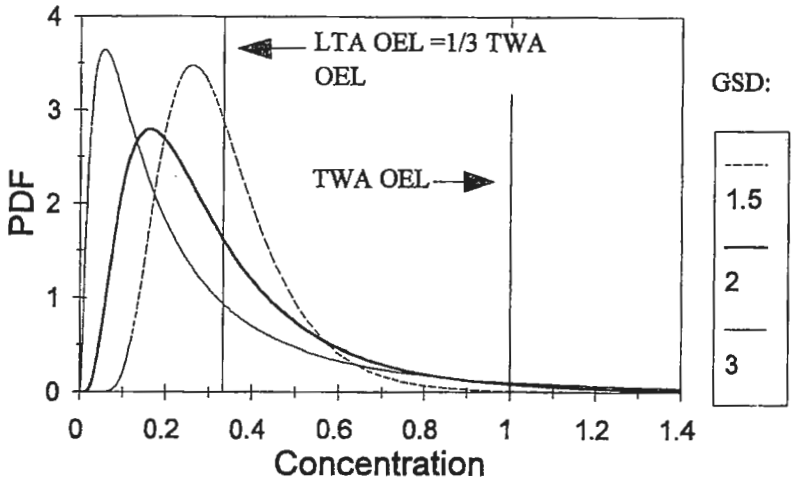

FIGURE 15.2 "Direct control" model. Hypothetical single-shift limit, or TWA OEL, is set at 1. The LTA (long-term) OEL is fixed at 1/3 the single shift OEL, per the recommendation of the AIHA (Ref. 5). (PDF = probability density function.)

GSD	*Mean*	*% > OEL*
1.5	0.333	0.2 %
2.0	0.333	2.7 %
3.0	0.333	6.1 %

be exceeded during any part of the working exposure."[20] In practical terms, if the true 99th percentile instantaneous or short-term exposure is less than the ceiling OEL, then one could reasonably conclude that the within-shift exposure profile was controlled during *that particular shift.*

An evaluation scheme based on the 95th percentile exposure is well suited to acute effect substances that may result in effects after roughly 15 minutes to several hours. Such substances will have either a short-term exposure limit (STEL) OEL or a TWA OEL (depending on the rapidity of action). For these substances it is important to control the dose across a short period of time. Average exposure across longer periods is less relevant because it is assumed that accumulation does not occur and that there is complete recovery before the next shift. If the true 95th percentile short-term exposure is less than the STEL OEL, then one could reasonably conclude that the within-shift exposure profile was controlled during *that particular shift.*

For chronic disease agents it is important to limit the cumulative dose acquired by the employee. Perhaps the most relevant exposure parameter is the long-term average exposure, which suggests that an exposure profile can be deemed "acceptable" if the true long-term average exposure is less than a long-term average OEL, or

TABLE 15.2 Working Statistical Definitions for OELs

Type of OEL	Working Statistical Definition	Supporting References
Ceiling	99th percentile instantaneous exposure or short-term (i.e., less than 15-minute) exposure within each shift	
STEL	95th percentile 15-minute exposure within each shift	2, 7, 8, 9, 20
TWA	95th percentile full-shift exposure	2, 6, 7, 8, 24, 31
LTA*	(a) 10%–25% of the TWA OEL	28, 29
	(b) 33% of the TWA OEL	2, 5

*The averaging time should not be more than one year for most work environments and no more than two years for stable work environments.

LTA OEL. However, few legal or authoritative LTA OELs have been developed.[24]* Instead, single-shift TWA OELs have been used to indirectly limit cumulative dose for chronic disease agents to presumably acceptable levels.[19] Properly implemented, single-shift limits will reduce the true long-term average exposure to a fraction of the TWA OEL. For example, Figure 15.1 depicts several typical lognormal distributions where the 95th percentile is equal to the TWA OEL. Using this "indirect" control model, the mean value of each distribution is approximately half or less of the TWA OEL.

In principle, a LTA OEL is useful for gauging whether or not the true average exposure of each employee is actually being limited to a reasonable value.[19] OSHA[12,25] has stated that in a controlled work environment the average exposure should be "well below" the OSHA PEL. How much less? The AIHA[2,5] suggested that in the absence of a legal or authoritative LTA OEL it is reasonable to set an LTA OEL for chronic disease agents at one-third of the single-shift TWA OEL. Others have suggested no more than half[26] or no more than one-tenth to one-fourth[27,28] of the single-shift limit. In the absence of a legal or authoritative LTA OEL, it is reasonable to use the AIHA recommendation of one-third the single-shift limit (or TWA OEL). Furthermore, as a general principle, at no time should the "measured" long-term average exceed one-half of the single-shift limit. Exposure profiles considered "acceptable" according to this "direct" control model are depicted in Figure 15.2.

Few so-called chronic disease agents solely produce chronic effects. For example, crystalline silica, usually considered a chronic toxicant, can also produce acute and accelerated silicosis, depending on the dose rate (frequency, duration, and severity of exposure).[29] Cadmium at lower levels is considered a chronic toxicant producing lung cancer and kidney disease, but excessive exposure within a single shift can cause life-threatening pneumonitis and pulmonary edema. For these and similar substances, it would be a mistake to assume that dose rate can be ignored. In other words, both the dose rate and cumulative dose are important, suggesting that *both* a single-shift OEL and long-term average OEL are necessary for properly judging an exposure profile. A single-shift limit would function as basically a "single-shift excursion limit" for a LTA OEL. The single-shift limit would be used to evaluate whether or not the exposure profile is *currently* controlled, by comparing each measurement, or the 95th percentile (or upper confidence limit on the 95th percentile) of a set of measurements, to the TWA OEL. The LTA OEL limit would be used to determine if, over each observation interval of 6 months to a year, the long-term mean of the exposure profile is adequately controlled. In practice, however, virtually all OELs are single-shift or short-term (e.g., 15-minute) limits.

*In many European nations the long-term OEL for vinyl chloride monomer is 3 ppm, while the single-shift TWA OEL is 7 ppm. Exposures should be controlled so that the long-term, annual limit is not exceeded.

Unacceptable Exposure Profiles

According to NIOSH, "no more than 5% of an employee's true daily exposure averages should exceed the standard."[7] The CEN (Comité Européen de Normalisation) recommends that corrective action take place if the exceedance fraction exceeds 5%.[6] The AIHA recommends that exposures be controlled to the point that only a small fraction exceeds the limit; for example, "no more than 5% of the exposures exceed the [OEL]."[5] Similar recommendations have been made by others (see Hewett[19] and Still and Wells[30]). Consequently, for the purposes of this chapter an unacceptable exposure profile is one where the probability of overexposure, or exceeding the OEL, is greater than 5%.

One should not infer from this discussion that exposures above an OEL can be ignored when the 95th percentile exposure is less than the OEL. As discussed later, standard industrial hygiene practice is to *investigate* each exposure above an OEL.[2,7,19,31] A measured overexposure is a signal that the work environment may have changed and is no longer acceptable.

Rating the Degree of Exposure Control

It is often useful, for risk communication purposes, to be able to state that exposures for an acceptable exposure group are "highly controlled," "well-controlled," or "controlled." It is also useful to be able to describe unacceptable exposure groups as "poorly-controlled" or "uncontrolled." In the absence of any official definitions for these terms, the "exposure categories" listed in Table 15.3 may be used. The "rule-of-thumb" descriptions for the categories were adapted from the AIHA monograph[5] on exposure assessment. The recommended statistical interpretations were designed to be consistent with the concepts of acceptable and unacceptable exposure profiles developed earlier in this chapter. For example, if the point estimate of the 95th percentile is less than half of the TWA OEL, then you would be justified in stating that exposures "appear to be well-controlled." If the 95% upper confidence limit (UCL) for the 95th percentile exposure is less than half of the TWA OEL, then you would be justified in stating that exposures "are well-controlled (with at least a 95% confidence)." The data analysis techniques discussed in Hewett[1] (Chapter 16) can be

TABLE 15.3 Exposure Category Rating Scheme

Exposure Category	Rule-of-Thumb Description*	Qualitative Description	Recommended Statistical Interpretation	Notes
Highly controlled	Employees have little or no inhalation contact	Exposures infrequently exceed 10% of the OEL	$P(c > 0.1 \cdot OEL) \leq 0.05$	1,2,3
Well controlled	Employees have frequent contact at low concentrations and rare contact at high concentrations	Exposures infrequently exceed 50% of the OEL and rarely exceed the OEL	$P(c > 0.5 \cdot OEL) \leq 0.05$ $P(c > OEL) \leq 0.01$	4,5,6 7
Controlled	Employees have frequent contact at low concentrations and infrequent contact at high concentrations	Exposures infrequently exceed the OEL	$P(c > OEL) \leq 0.05$	8
Poorly controlled	Employees often have contact at high concentrations	Exposures frequently exceed the OEL	$P(c > OEL) > 0.05$	9
Uncontrolled	Employees frequently have contact at high concentrations	A large percentage of the exposures exceed the OEL	$P(c > OEL) >> 0.05$	10,11

Note. c refers to an 8-hour TWA exposure concentration or a short-term exposure concentration. OEL refers to the TWA OEL or STEL OEL. The term exposures should be read as exposures of each employee.

*The rule-of-thumb descriptions were adapted from the AIHA (1991).

1. Infrequently refers to an event that occurs no more than 5% of the time.
2. $P(c > 0.1OEL) \leq 0.05$ is read as the probability that an exposure (c) is greater than one-tenth the OEL and is less than or equal to 0.05.
3. Alternative statistical definition: 95th percentile $\leq 0.1 \cdot$ OEL.
4. High concentrations are defined as concentrations that exceed the TWA OEL or STEL OEL.
5. Rarely refers to an event that occurs no more than 1% of the time.
6. Alternative statistical interpretation: 95th percentile $\leq 0.5 \cdot$ OEL.
7. Alternative statistical interpretation: 99th percentile $\leq$ OEL.
8. Alternative statistical interpretation: 95th percentile $\leq$ OEL.
9. Alternative statistical interpretation: 95th percentile > OEL.
10. Alternative statistical interpretation: 95th percentile $\gg$ OEL.
11. Exposures are considered largely uncontrolled if the point estimate of the exceedance fraction is much greater than 0.05. For example, a point estimate of an exceedance fraction of 0.25 would clearly indicate that exposures are uncontrolled.

used to determine if an exposure profile meets the criteria for a "highly-controlled," "well-controlled," or "controlled" rating.

Comments

What Does It Mean to Be "In Compliance"?

The term "in compliance" has sometimes been defined to narrowly refer to the situation where each of a small number of measurements is less than the applicable OEL, federal or otherwise. Tuggle[32] showed how unacceptable work environments can often be declared "in compliance" when the sample size is small. For this reason professional industrial hygienists[2,5,6,8,30] advocate the collection of sufficient measurements to evaluate exposure profiles. Consequently, readers are encouraged to equate the concept "in compliance" with the concept, previously discussed, of an "acceptable exposure profile" for each worker. An "acceptable exposure profile" indicates that the individual long-term mean exposure, single-shift excursions above the OEL, and the probability of a citation are controlled to arguably acceptable values.[19]

Other Interpretations

It should be noted that the interpretations presented here regarding the ACGIH TLVs and OSHA PELs for chronic disease agents are not shared by all.[9,10] There are those who believe that these exposure limits should be interpreted as upper control limits to the long-term average exposure. Hewett[24] argues that there is abundant evidence that the ACGIH TLVs and OSHA PELs for chronic disease agents were and are intended to be interpreted as upper control limits for each single shift, and not upper limits for long-term, lifetime average exposure as some maintain. However, the documentation for a particular OEL should be consulted to determine the

proper interpretation before designing an exposure monitoring program.

Exposure Monitoring Programs

Once it is determined that a quantitative exposure assessment is necessary, a written, documented exposure-monitoring program should be developed.[2,5] An exposure-monitoring program should cover the four hazard evaluation components: (a) data collection, (b) data analysis, (c) data interpretation, and (d) data management. First, it is necessary to clearly establish the goal for an exposure-monitoring program, regardless of its actual design.

Goal of an Effective Exposure-Monitoring Program

It is important that the collection and interpretation of exposure measurements result in the *correct* classification of the work environment for each exposure group, and not grossly underestimate or overestimate the exposures of any employee within each exposure group. Consequently, the goal of an effective exposure-monitoring program is to *periodically* obtain *sufficient*, *valid* and *representative* exposure measurements so that the *work environment* for each *worker* is *reliably classified* as either *acceptable* or *unacceptable*. Each italic term is explained below.

"Periodically"

Since few industrial processes remain constant for extended periods (months to years) exposure profiles should be expected to change over time.[33] For example, processes change, production levels vary, ventilation systems degrade, new workers are introduced, and tasks and work practices vary. Exposure sampling should occur frequently enough that a significant and deleterious change in either the contaminant generation process or the efficacy of the exposure controls is not permitted to persist for long.

"Sufficient"

The industrial hygienist should collect a sufficient number of measurements so that uncontrolled work environments are reliably detected. A critical attribute of a dataset, or collection of exposure measurements, is its predictive value for each member of the exposure group. A single exposure measurement that is under the OEL has limited predictive value when attempting to demonstrate that a work environment is (and is likely to remain) acceptable.* On the other hand, a single overexposure occurring by itself, or in a small dataset, is highly suggestive that exposures may be poorly controlled or uncontrolled.[19] A collection or sample of exposure measurements has better predictive value.

"Valid and Representative"

A valid exposure measurement is one that is collected using a reasonably accurate sampling and analytical method and at a location that permits a reasonable estimate of the selected employee's personal exposure. When characterizing the exposure profile of an exposure group, measurements should be representative in the sense that (a) production levels, environmental controls, and work practices were not manipulated or optimized for the benefit of the survey; (b) the work environment is reasonably stable within each observation interval; and (c) measurements were collected in a random fashion (i.e., the sample days were randomly selected).

Practically speaking, however, nonrepresentative sampling has its uses. It is both reasonable and efficient to collect measurements solely on days of expected maximal exposure and/or solely from employees known or suspected to routinely experience the greatest exposures.† It is also reasonable in many industrial environments to collect measurements in campaign fashion (i.e., on consecutive days), rather than in a strictly random fashion, because in most cases there is little serial correlation between measurements.[34] When evaluating exposures relative to a short-term OEL or ceiling limit OEL, the usual strategy is to purposefully sample during periods that are representative of peak or maximum probable exposures.[2,34]

"Work Environment"

We are interested in rating the quality of the work environment for each exposure group. The work environment can be defined as the physical space in which the members of the exposure group spends the majority of their time, or it can be more abstract and refer to a specific combination of exposure agent, shift, job, task, and work area.

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*A single exposure measurement that is extremely low, e.g., less than 10% of the TWA PEL or STEL, can have considerable predictive value *provided* the day, employee, shift, and task (when comparing short term exposures to the STEL) represents a worst case exposure.

†The term "representative employee" is often used to by OSHA to refer to the maximum-risk employee.

"Worker"

Both common sense and federal law[35,36] dictate that each worker should expect a work environment devoid of unreasonable risks. While we recognize that our goal is to protect *each* individual worker, limited resources compel industrial hygienists to (a) aggregate workers into exposure groups; (b) determine which exposure groups warrant priority attention[2,5]; and (c) evaluate the "exposure profile" of each exposure group in order of priority.[2,5,8] Consequently, our data-collection strategies, and data analysis and interpretation procedures must be designed so that our *conclusions* regarding the exposure group are reasonably *predictive* of the exposures experienced by each member of the group.

"Reliably Classified"

A properly designed exposure-monitoring program will have a high probability of classifying a work environment as acceptable when the exposure profile is truly acceptable (according to some definition of acceptable), and a high probability of classifying the work environment as unacceptable when the exposure profile is clearly unacceptable. It may be difficult to design a program that maximizes both probabilities, in which case the program design should focus on maximizing the latter probability. This is discussed in more detail in the section on program performance characteristics below.

"Acceptable or Unacceptable"

Exposures (i.e., the exposure profile) for an exposure group are classified as either *acceptable* or *unacceptable*. Acceptable exposures can be described qualitatively as either minimal, well controlled, or controlled. Unacceptable exposures are either poorly controlled or uncontrolled (Table 15.3). The determination, after a baseline survey, that the exposure profile is acceptable for an exposure group *does not* automatically imply that the exposure profiles for all group members are also acceptable. As discussed below, periodic follow-up surveys and random sampling of all group members is commonly used to verify that maximum-risk employees have not been overlooked. This, combined with task-analysis and control of within-shift peak exposures, tends to ensure that the assessment of the group exposure profile is sufficiently predictive of the exposure experiences of all group members.

Prioritization

The number of unique exposure groups—or agent/process/job/area combinations—can be considerable for most workplaces. However, in instances of mixed exposures it is often permissible to select one or more *index* compounds for measurement and control. Exposures to other less toxic, less hazardous, or difficult-to-measure substances are likewise reduced and controlled.

Several schemes have been advanced for prioritizing between exposure groups. In 1991 the AIHA Exposure Assessment Strategies Committee[5] recommended the use of a "health-effect rating" and an "exposure rating" (see also Rock[31]). More recently the AIHA introduced the concept of "critical exposure group" to refer to exposure groups that should be evaluated first.[2] Similar schemes have been found useful by many corporations and have become an integral part of what the AIHA[2] refers to as "comprehensive exposure assessment."

Critical Concepts

Observation Intervals

"Observation interval," or "survey period,"[30] refers to the length of time until the next re-sampling survey. It is necessary that during this time the exposure profile remain reasonably stationary. Otherwise, the results of the last survey will have little to no predictive value. The observation interval may vary with exposure group, depending on the nature of the process, cycles and trends in production, the rate of worker turnover, and the maintenance and upkeep of existing controls. The observation interval may be as short as a few days or weeks for highly dynamic work environments, and as long as a year or more for well-controlled, highly stable work environments. For acutely toxic substances the observation interval can be as short as a single day; in other words, exposure monitoring takes place daily.

A key feature of the observation interval concept is that measurements collected during the *current* observation interval are usually the most important for predicting future exposures. Current high exposures should not be combined with measurements from the previous interval in order to produce an "acceptable" exposure profile. The current high exposures indicate that the exposure profile may no longer be adequately controlled and that future exposures may be excessive.

Program Performance Characteristics

The problems of exposure management are similar to those in maintaining quality control in a manufacturing process. The ability of a quality control procedure to detect *acceptable* and *unacceptable* manufactured products or lots is described by the procedure's Performance or Operating Characteristic curve.[37] It is possible to deter-

mine the performance characteristics for any exposure-monitoring program. For example, Tuggle[32] presented the performance curve for the NIOSH sampling strategy and decision logic. He showed that the probability of incorrectly concluding that the work environment is acceptable was quite high, even when the exceedance fraction is clearly unacceptable, that is, 0.25 or greater. Since the NIOSH strategy and decision logic has been incorporated into numerous OSHA 6(b) single-substance standards, this suggests that an exposure-monitoring program based on such minimalistic requirements will often misclassify work environments as acceptable when in fact the true exceedance fraction exceeds 0.05.

Computer simulation may be required to determine the operating characteristic curve for most exposure monitoring programs and so is not often done. However, it is important to recognize that for any exposure-monitoring program there are two "risks" that can be minimized: the "employer's risk" and the "employees' risk." Employer's risk refers to the probability of *incorrectly* concluding that the work environment for an exposure group is unacceptable, when indeed the true exposure profile is acceptable. Employees' risk refers to the situation where the work environment has been *incorrectly* judged to be acceptable, when in fact the true exposure profile is unacceptable. Note that the Employees' Risk *does not necessarily correspond to the risk of developing disease.* It refers to the fact that it is the employees that are affected when an unacceptable level of overexposures remains undetected for the observation interval. In traditional terms, employer's risk corresponds to the α-error (Type I error) for the exposure monitoring program, while employees' risk refers to the β error (Type II error).

The conscientious employer will always design an exposure-monitoring program that focuses on minimizing the employees' risk. This is because any decision that results from the analysis of a finite set of exposure data is extrapolated in two ways. First, the decision is extrapolated to all unmeasured employees in the exposure group. If the decision is wrong, it can potentially affect a great many employees. Second, the decision is extrapolated into the future for the entire exposure group for the entire duration of the observation interval, that is, until the collection of the next set of exposure measurements. If the decision is wrong, it will affect the entire exposure group for what may be an extended interval.

It is entirely logical to design an exposure-monitoring program that is concerned with minimizing employees' risk and tolerating a rather large employer's risk. This is because the employer's risk does not correspond to the probability of implementing expensive, potentially unneeded controls. Employers usually *verify* the presence of an unacceptable exposure profile with one or more follow-up surveys before implementing expensive controls.

Exposure Histories

Over time an "exposure history" will develop for each exposure group. This exposure history can be used to detect long-term trends or to evaluate cyclic patterns of exposure associated with production trends or seasonal variations. Exposure histories also allow you to "calibrate" your industrial hygiene judgment regarding the stability or variability associated with various processes, operations, or tasks. Furthermore, consistently low measurements from year to year, even when only a few measurements are collected per year, can provide convincing evidence that exposures were, and are likely to continue to be, "acceptable." Periodic task analysis should also help improve group homogeneity, so that the exposure experience of the group is more predictive of each group member.

Data Collection

Data collection requires a sampling strategy that specifies the type of survey and the process for selecting whom to monitor within each group, how many measurements to collect, and how often or under what conditions this process is repeated. The sampling strategy should specify the approximate frequency of periodic reassessments and the conditions that will trigger a special reassessment. Periodic surveys have a dual purpose. First, resampling is essential for verifying that the earlier assessment was correct. Second, resampling is often the only means of detecting a trend toward increasing exposures. There are several types of sampling strategies and at least five types of exposure-monitoring surveys.

Sampling Strategies

There are four generic sampling strategies: individual based, maximum-exposed employee based, high-risk activity or task based, and exposure group based. Hybrid combinations are always possible and, in fact, commonplace. Sampling strategies based on the exposure group concept are prominently featured in the recommendations of authoritative organizations, such as the AIHA[2,5] and CEN.[8]

Individual Based

Ideally, the exposures experienced by each employee should be regularly estimated, preferably by numerous

exposure measurements collected either in campaign fashion (i.e., within a short period of time or during consecutive shifts) or across several months. For some occupations or work environments, where there are only a few workers and exposures range from significant (e.g., greater than 10% of the OEL) to "poorly controlled" (see Table 15.3), it may be necessary to periodically monitor 100% of the workers. Each employee basically constitutes a single exposure group.

Strategies that involve the regular monitoring of all exposed employees are, for practical reasons, not often implemented. However, it is important to recognize that regardless of the type of strategy adopted out of expediency or due to limited resources, the goal of an exposure-monitoring program is to make accurate *decisions* regarding the exposure profile of *each* employee.

Maximum-Risk Employee Based

Strategies that focus on the maximum-risk employees (MREs) in each exposure group are based on the idea that if the MRE exposures are judged acceptable, then it is logical to assume that the *all workers within the group* are adequately protected. For example, in the mid-1970s NIOSH[7] developed a sampling strategy and decision logic that featured (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. It was designed to impose a "minimum burden to the employer [i.e., risk manager] while providing adequate protection to the exposed employees," but had several weaknesses. For example, the ability of industrial hygienists to reliably select one or more maximum-risk employees from an exposure group has been questioned by several researchers. Furthermore, the NIOSH strategy will not reliably detect unacceptable work environments, even when the true exceedance fraction greatly exceeds 0.05.[32] Consequently, one should view the NIOSH scheme as the basis for a minimalistic exposure-monitoring program that is best suited for *auditing* work environments where exposures were previously determined, by a comprehensive exposure assessment, to be controlled, well-controlled, or minimal.

Slightly modified versions of this strategy were incorporated into OSHA's single substance 6(b) standards (e.g., lead, benzene, asbestos, formaldehyde, among others). OSHA also recognized that such a strategy represented a "token" commitment that will not accurately classify all work environments.[34] Nonetheless, for initial evaluations or where resources are limited or re-sampling intervals are broad, the MRE concept is still recommended and commonly used by industrial hygienists as a means of efficiently determining the acceptability of the work environment for the members of an exposure group.

High-Risk Activity or Task Based

Investigators are increasingly interested in determining which task (i.e., component of a job) or work practice contributes most to the worker's overall exposure.[38–42] Once a particular task or work practice is identified as the primary contributor to exposure, it is often possible to substantially reduce the daily average exposure by adding task-specific controls and/or through the modification of individual or group work practices.

Exposure Group Based

A common exposure sampling strategy involves the concept of "homogeneous exposure groups"[5] or "similar exposure group."[2] Basically, workers are aggregated on the basis of work similarity, exposure agent(s), environment (workplace, process, task, and controls) similarity, and identifiability.[6] One or more measurements are collected from each of n randomly selected workers per exposure group. This strategy was designed for efficiency; that is, 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. Such a strategy is implicitly based on the concept that effective occupational exposure management for the exposure group results in effect exposure management for each member of the group.

In 1991 the AIHA Exposure Assessment Strategies Committee presented the "homogeneous exposure group" (HEG) concept.[5] In theory, workers in an HEG have "identical probabilities of exposure to a single environmental agent." However, the committee recognized that exposures on any single day will vary from worker to worker. Furthermore, in practice, the individual exposure profiles are expected to be similar, but not identical. For an initial or baseline evaluation the industrial hygienist should randomly select 6–10 workers per HEG and collect 6–10 measurements over a relatively short period 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 environ-

ment."* Exposures for an HEG are usually deemed acceptable if it is highly likely that 95% of the measurements are less than the OEL (determined using upper tolerance limits). The Committee now uses the phrase "similar exposure group,"[2] but the general concept remains the same.

The European standard for exposure assessment adopted by the CEN[6] 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.† This standard recommends 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 overexposure 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 overexposure remains less than 5%.

Exposure group–based strategies are best suited to exposure groups that are reasonably homogeneous; that is, there are 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 overexposed.[6] Several researchers have shown that exposure groups often have a great deal of between-worker variability.[43,44] Consequently, this assumption may not be valid without an analysis of objective data. For this reason, occasional random sampling of all members of an exposure group is advised in order to assess the degree of group heterogeneity. In addition, as noted previously, task and work practice analysis is expected to decrease between-worker differences in exposure, thus making the group experience more predictive of individual experiences.‡

*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.

†[I]f an individual exposure is less than half or greater than twice the arithmetic mean [for the HEG], the relevant work factors should be closely re-examined to determine whether the assumption of homogeneity was correct."

‡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 (see Ref. 10).

Sampling Surveys

For each of the above sampling strategies an individual survey will tend to fall into one of the following categories: (1) baseline, (2) surveillance, (3) audit, (4) research (epidemiological), and (5) diagnostic. For baseline, surveillance, and audit surveys, the goal of the survey may be to merely demonstrate "compliance" with the minimalistic requirements of federal or state regulations. Or the goal of the survey may be to accurately characterize the exposure profile of each exposure group or for the maximum risk employees within each group. Harris[45] and the AIHA[2,5] provided expanded discussions regarding these surveys. Harris in particular recommends several "levels" of effort where measurements are collected to satisfy both compliance and research (risk-assessment) needs.

Baseline

A baseline or initial-exposure sampling survey is intended to collect sufficient exposure measurements to accurately characterize and judge the exposure profile of an exposure group. Consequently, one should be concerned with forming reasonably accurate exposure groups and with collecting sufficient measurements per group. For example, the AIHA[2,5] recommends that at least 6–10 measurements are required for a baseline evaluation. In principle, *a new baseline survey* is required whenever there are changes that have the potential to significantly alter the exposure profile of the exposure group. These changes include production level changes; seasonal effects; introduction of new workers; deterioration of existing controls; changes in job descriptions, tasks, and/or work practices, to name a few. For example, the effectiveness of general dilution ventilation and local exhaust controls can vary substantially between summer and winter months.

Surveillance

The routine monitoring that occurs after a baseline survey can be considered surveillance sampling. Sufficient measurements should be collected in a timely fashion so that trends are identified and the initial exposure rating of the exposure group is validated. The frequency of monitoring depends on the stability of the process and the degree of existing control. Routine quantitative exposure surveys or exposure surveillance monitoring may not be the best choice in those situations where exposures are just marginally controlled (i.e., point estimate of the exceedance fraction is less than but near 0.05). In such situations, it is entirely possible that the cost of reg-

ular monitoring and surveillance activities approaches or exceeds the cost of effective controls.[2]

Audit

An audit survey, as distinguished from a surveillance survey, is conducted by outside investigators, such as corporate level inspectors or compliance officers from a regulatory agency. It is intended to quickly check for evidence that the exposure profile for an exposure group is unacceptable. This is often accomplished by selecting and monitoring one or more maximum-exposure employees or tasks. If the exposure of this employee is above the OEL, then it is reasonable to assume that this and other employees may be routinely overexposed. The company is then obligated to initiate a more comprehensive evaluation, such as is done during baseline surveys, and take remedial action if warranted.

Research (Risk Assessment)

Many companies participate in cohort studies or recognize that well-developed exposure databases are necessary for future risk assessments.[45] Since a goal of these studies is to determine the exposure-response relationship for a particular substance, it is necessary to routinely and accurately characterize the exposure profile for each exposure group—regardless of exposure level—included in the study cohort during each observation period of the study. A common observation period is a year interval.

Diagnostic

A diagnostic survey is designed to locate the source of exposure, identify the task or activity that contributes most to exposure, and test the efficacy of a control. In general, short-term measurements or direct reading instruments are used and the time and location are often deliberately selected in order to measure maximum within-shift exposures. Such measurements should not be used when estimating the exposure profile for an exposure group, but can be used for prioritizing between groups when allocating limited industrial hygiene resources.

Data Collection Issues

In 1973 Hosey[46] suggested that industrial hygienists address five questions before collecting measurements that are reasonably representative of worker exposures.

- Where to sample?
- Whom to sample?
- How long to sample?
- How many measurements to collect?
- What shift to sample?

At that time industrial hygienists typically collected short-term, or "grab sample" measurements, even when evaluating full-shift exposures. Since then instrumentation has improved, permitting the collection of full-shift exposure measurements using personal, battery-powered sampling pumps or direct-reading devices with data-logging capabilities. Consequently, our answers to the above questions may differ somewhat from those first proposed by Hosey. Furthermore, we can add several additional questions to the list:

- What season to collect measurements?
- When to resample?
- When to reduce sampling?

Sample Location

When measuring exposures for comparison with a TWA, STEL, or Ceiling OEL, the usual procedure is to place a reasonably accurate exposure-measuring device on the worker, within the worker's breathing zone.* There are instances where area sampling locations are reasonably predictive of individual worker exposures; however, before using general area exposure measurements to assess the quality of risk management for individual workers you should first determine the degree of correlation between personal and area measurements.

Worker Selection

Random selection is recommended when the goal is to characterize the exposure profile of an exposure group.[2,5,8] In reality, true "statistically based" random selection is seldom practiced. The phrase "representative employee" is often encountered in OSHA 6(b) (single substance) regulations to refer to the employee expected to have the highest exposure. Although some authorities question whether or not an industrial hygienist can reliably select this "representative employee," also called the maximum-risk employee, the selection of the employee "closest to the source of the hazardous material being

*The breathing zone has been variously defined as a sphere or hemisphere with a six inch to two foot radius about a worker's head. The concept behind the various definitions is that an individual worker's exposure is best estimated by a sampling device placed as close to the worker's mouth and nose as is reasonable and safe. Typically, a sampling device is clipped to the worker's left or right lapel.

generated"[7] is an often used technique to efficiently evaluate a work environment.

Measurement Averaging Time

The averaging time for the majority of TWA OELs is 8 hours and 15 minutes or less for short-term exposure limits and ceiling OELs. In order to combine measurements for data analysis it is essential that the averaging time, sampling methodology, and sampling strategies be similar for each measurement in the dataset.[7] Unless the averaging times are nearly identical, the sample geometric mean and geometric standard deviation (discussed in Chapter 16) may be misleading and lead to incorrect decisions. For example, it would be improper to mix 15-minute STEL and full-shift TWA measurements. Furthermore, measurements collected for substantially different purposes usually should not be combined. For example, measurements collected from randomly selected employees should not be combined with measurements collected from one or more purposefully selected maximum-risk employees.

Sample Size

How many measurements are necessary to adequately characterize an exposure profile? There is no easy answer. Strict use of rigorous sample size formulae often leads to sample size estimates—*per individual worker or exposure group*—well beyond the reach of most exposure monitoring programs.[48] Several consecutive, partial-shift "industrial hygiene samples" may be required just to generate a single full-shift TWA measurement. For a LTA OEL, where the relevant averaging time is no more than one year, *n* full-shift TWA measurements are necessary before one can calculate a single "measurement" of long-term exposure.[19,47]

For TWA OELs and baseline or initial-exposure surveys there are several *rules-of-thumb*. For example, the CEN[6] recommended a minimum of six measurements before using "statistical principles" to evaluate the exposure profile of an exposure group. The AIHA[2,5] recommended 6–10 measurements for baseline evaluations, but cautioned that the accurate estimation of the true 95th percentile may require a much larger sampling commitment. Ayer[49] recommended that "the number of samples [i.e., measurements] in a sampling round equal the square root of number of workers." For surveillance or periodic monitoring Roach[50] recommended that "1 in 25 or 1 in 50" shifts be monitored when exposures exceed 10% of the OEL. Hewett and Ganser[51] suggested a method for relating the sample size to the desired width of the confidence interval around the point estimate of the exceedance fraction.

In summary, there is no easy answer or magical sample size formula applicable to all situations. The above cited *rules-of-thumb* provide general guidance. If exposures are expected to be minimal, then it is reasonable to limit the sample size and devote resources to more problematic exposure groups. Marginally controlled work environments should receive more attention. Work environments known to be poorly controlled or uncontrolled are unlikely to benefit from additional sampling. Controls should be implemented and consideration given to interim worker protection through the use of personal protective equipment.

Shift Selection

Frequently there is more than one shift and the work on each shift is functionally identical. However, one should not automatically assume that the two shifts constitute a single exposure group. OSHA's 6(b) standards generally require that measurements be taken on each shift:

> Representative samples for each job classification in each work area shall be taken for each shift unless the employer can document with objective data that exposure levels for a given job classification are equivalent for different work shifts.[34]

This regulation constitutes generally sound advice. For example, Rock[31] described a situation where there were significant differences in the exposure profiles between day and night shift painters. Measurements collected exclusively from the day shift would have severely underestimated night shift exposures.

Time of Year

It is generally accepted that indoor exposures tend to be greater during the colder months. Doors are generally closed and ventilation systems lose effectiveness. As with shift, one should not assume that measurements collected during one season are representative of all seasons. When in doubt, baseline exposure monitoring should occur several times during the first year, until an exposure history is developed.

Frequency of Re-sampling

Roach[50] recommended that "an appraisal should be made each month of one or more employee's exposure over one shift" for each exposure group where measurements are routinely between 10% and the OEL. Corn[52]

recommended resampling frequencies ranging between 3 and 12 months, depending on past results, confidence in the engineering controls, and the toxicity of the substance. The AIHA[2,5] recommended periodic reevaluations at least annually for each exposure group.

Resampling should also take place anytime there is a change in process, tasks, production levels, and ventilation controls that may result in new or additional exposures. Furthermore, "immediate" reevaluation is warranted if there is an employee complaint, a process change, and any "real or suspected occupational illness."[2,5] Reevaluation may also be necessary when significant new toxicological data or regulatory changes occur.

The CEN[6] recommended resampling even when a baseline survey shows that exposures are below the OEL:

> [S]ubsequent measurements at appropriate intervals should, if necessary, be taken to ensure that the situation continues to prevail. The nearer the concentration recorded comes to the limit value, the more frequently measurements should be taken.

The CEN then provided two examples of decision schemes for determining the number of measurements and sampling frequency for an exposure group that has already undergone a comprehensive exposure assessment.

As a general principle a follow-up survey should be conducted after every initial or baseline exposure assessment to verify that the initial or baseline exposure assessment was correct. Each exposure group should be reevaluated at least once per year, and more often if the work environment is particularly variable. This reevaluation may involve simply updating the background information for this exposure group. However, a new baseline survey is warranted if there are indications that the process has changed, controls have deteriorated or are no longer effective, or that work practices or job tasks have changed.

Reduction of Sampling

Roach[50] recommended that the frequency of resampling be reduced to once every 2 months when exposures are consistently controlled to below one-third of the OEL. Exposures consistently below one tenth of the OEL require only an occasional evaluation, and then focused on checking the ventilation system and detecting "process leaks."

OSHA 6(b) standards often specify the conditions for reducing the sampling burden. For example[34]:

> The employer may discontinue periodic monitoring if results from two consecutive sampling periods at least 7 days apart show that employee exposure is below the action level [i.e., 50% of the standard] and the STEL.

According to the CEN,[6] if the exceedance fraction 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.

Comments

Regulatory Compliance Sampling Strategies

In the United States most federal regulations require that employers collect only one or a few measurements per exposure group, and usually from one or more maximum-risk employees (when they can be reliably identified). These measurements are not required to be evaluated and interpreted using statistical techniques such as described here, but are merely compared to the legal OEL. Such minimalistic strategies will reliably render the correct decision only when exposures are already "minimal," "well-controlled," or grossly "uncontrolled."[19,32] Industrial hygienists should be aware that the strict, uncritical application of these minimalistic mandatory requirements can often lead to the incorrect conclusion that exposures are acceptable. Consequently, there is considerable room for voluntary improvement and enhancement, as OSHA intimated in Appendix B of the 1992 final standard for formaldehyde.[53] Exposure profile analysis, as advocated by the AIHA,[2,5] the CEN,[6] and numerous authorities is preferred (see related discussion in Hewett[19]).

Data Management

Each datum generated by an exposure-monitoring program should be documented and stored in a database of some sort, along with the descriptive information necessary for giving meaning to that number. Industrial hygienists recognize that there is considerable potential associated with maintaining databases of exposure data and with sharing these data with trade organizations, academia, and federal agencies.[54] The many potential uses include[55]:

- assessing compliance with applicable OELs
- assessment of control measures: exposure data can be used to monitor the continued effectiveness of existing control measures or for developing cost-effective controls

- risk assessment: exposure databases are critical to exposure-response epidemiological studies
- regulatory risk management: exposure databases can be used to develop "better informed" regulatory policies and guidance
- risk communication: such databases can be used to effectively and accurately communicate risk evaluations to employers, employees, and regulatory agencies

One of the tasks facing those developing company, corporate, industry or trade organization, or national and international exposure databases is the identification of the "essential data elements." Table 15.4 contains the major categories of essential data elements as suggested by a joint ACGIH-AIHA Task Group on Occupational Exposure Databases[56] and a European working group.[57] Both articles include an overview of the relevant literature and provide recommendations for developing an effective exposure data management program.

The common feature of these proposals is the concept of "accountability." Each risk manager (e.g., industrial hygienist) should (a) continuously document all critical decisions, such as the criteria for defining and refining exposure groups; and (b) maintain relevant exposure information for use by risk managers and/or researchers in the years to follow.

Along similar lines, the AIHA Exposure Assessment Strategies Committee[2] recommends that exposure data be managed using six relational databases:

1. workplace data—workplace description, process flowcharts, floor plans, etc.
2. environmental agent data—an inventory of the chemical, physical, and biological agents present
3. similar exposure group data—basis for establishing each exposure group
4. worker data—data for linking specific workers to each exposure group for each observation period
5. exposure assessment data—relevant data regarding each exposure assessment to include the interpretation of the data (i.e., acceptable, unacceptable, or uncertain)
6. monitoring data—the data relevant to each exposure measurement (e.g., date collected, location, sampled worker)

Setting up such database systems is not a trivial task and sometimes takes years. But once in place such systems permit the analysis of exposure trends, efficient targeting of resources, effective communication of exposure analyzes to workers and management, documentation of remedial actions, and documentation of effective exposure control.

TABLE 15.4 Suggested Major Categories for the Essential Data Elements in an Occupational Exposure Database

ACGIH-AIHA Task Group[57]	Rajan et al.[56]
Facility/site	Premises
Survey tracking (e.g., original report)	Workplace
Work area	Worker activity
Employee information	Product
Process and operation	Chemical agent
Chemical agent information	Exposure modifiers
Exposure modifiers	Measurement strategy
Sample information	Measurement procedure
Sampling device information	Results
Engineering controls	References (e.g., original report)
Personal protective equipment	
Results: chemical, noise	

Note. The references describe the data elements associated with each category.

Additional Issues

Nontraditional Work Schedules

Brief and Scala[57] observed that the TLVs were designed for a traditional 8-hour work shift and 40-hour workweek. They introduced a conservative method for *reducing* the TLVs to reflect a "novel" work schedule. Extended work shifts and/or more than 40 hours of exposure per week reduce the "recovery" time for each worker and "stretch the reliability and even viability of the data base for the TLV."[58] The ACGIH[59] recommends that, among other models, the "Brief and Scala model" be used as guidance for reducing the TLV when there is a nontraditional work schedule. OSHA specified a simpler scheme for the 1978 lead[60] and the 1994 cadmium[61] PELs.

Sampling and Analytical Error versus Environmental Variability

All sampling and analytical methods yield estimates of exposure that vary somewhat from the true exposure at the location of the sampling device. The overall accuracy of a sampling and analytical method depends on the imprecision and bias* of the method. NIOSH[62] considers a method sufficiently accurate if, after accounting for bias and imprecision, it will yield an estimate that is within

*Sampling and analytical methods for organic chemicals often have less than 100% recovery of the substance, resulting in a negative bias in the calculated exposures.

plus or minus 25% of the true concentration (within a range of one-half to twice the PEL) 95% of the time.

Exposure measurements collected from day to day often vary considerably, reflecting the variability in the process parameters, production rate, variations in the daily operation of the exposure controls, individual work practices, and so on. The normal random errors in the sampling and analytical method will contribute somewhat to the day to day (between-day) variability in exposures. However, this contribution is usually inconsequential.[63] In other words, if an exposure exceeds the TWA PEL or STEL it is more likely due to work-related factors than to errors arising from the sampling and analytical method. For this reason, the conscientious employer will *investigate* any overexposure for *assignable* causes that possibly can be easily rectified.

Suggested Reading

Comprehensive Exposure Assessment

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