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A Strategy for Assessing and Managing Occupational Exposures

Fourth Edition

IH professionals will find this newly updated resource beneficial in allocating resources for assessing and managing occupational exposures to chemical, physical, and biological agents.

Edited by Steven D. Jahn, William H. Bullock, and Joselito S. Ignacio

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Introduction

By John Mulhausen, PhD, CIH, CSP, FAIHA and Joseph Damiano, MS, CIH, CSP, FAIHA

Why Is Exposure Assessment Important?

Industrial hygiene is defined as the science and art of anticipating, recognizing, evaluating, controlling and confirming health hazards in the workplace. Clearly the identification, characterization, and assessment of exposures is implied in this traditional definition, so why spend all this effort producing a book about what industrial hygienists have been doing for years?

The answers lie in an examination of the growing number of real and perceived risks and changing social requirements that industrial hygiene programs must be prepared to manage, and in the approaches that will be effective in understanding and managing those risks. Industrial hygiene programs today must be prepared to manage a broader range of risks than in the past. The standards to which those programs are held accountable have increased. Whereas in the past programs could be less rigorous, they must now be thorough, systematic, well-documented, effective, and efficient.

Growing Variety of Present and Future Risks

Workplaces today are very complex. The variety of risks associated with workplace exposure to chemical, physical, and biological agents is increasing. Although the first priority of the industrial hygienist is to protect the health of workers, health risk is not the only risk he or she is asked to manage. Others would be regulatory risks, legal risks, and risks related to the anxiety inherently associated with many people's response to exposures.

Industrial hygienists must consider that organizations today are accountable to many more — and more varied — stakeholders than in the past. These new stakeholders include employees, owners, customers, labor unions, regulators, stockholders, the press, and the communities in which the organization operates. Industrial hygienists are relied on to satisfy the workplace exposure concerns of these stakeholders.

When evaluating risk to employees and the organization, industrial hygienists must remember that their programs will be held accountable not only for today's state of the art but tomorrow's as well. It is not sufficient to limit the question to:

"Are employee exposures below established exposure limits?" Instead, industrial hygienists must ensure that exposures are characterized well enough — and controlled well enough — to keep present risks within acceptable limits and to put the organization in the position to manage future risks. Among the questions that must be considered are:

- How might this exposure affect employee health?
- Is the exposure limit adequate?
- What other risks are presented by this exposure?

Compliance with current limits is not sufficient. Most chemicals have no occupational exposure limits, and the information used to set existing limits is often incomplete. Also, existing limits are not always designed to protect the most sensitive workers. These limits might even be out of date. Economic and technological factors are considered when OSHA passes a new standard.

Each day, new toxicological and epidemiological information is gathered. This means new exposure limits will be generated for environmental agents that formerly had none, and that many of the limits currently in place will change. Experience has shown that most exposure limits are lowered when they are changed, and there is no reason to believe that trend will not continue.

Unfortunately, when new limits are set or old limits are changed, there may be a population of workers who have been exposed to an environmental agent for some time at levels above the new limit. Industrial hygienists today must focus on how to position their programs so they are best able to manage changes and minimize any future risks. Having a historical database for all exposures should allow identification of employees who were exposed above the lowered exposure limit and enable the extent of their past overexposures to be estimated. An appropriate strategy could then be developed for medical management of the health of those employees.

Efficient and Effective Programs

At the same time industrial hygienists are being asked to manage a growing variety of risks, the efficacy, efficiency, and cost-effectiveness of their programs are being scrutinized more carefully. Economic factors demand that each organizational unit demonstrate its worth and its ability to operate waste-free — industrial hygiene programs are no exception. The ability to understand, prioritize, and manage exposures and risks efficiently requires a more systematic, better-documented approach to industrial hygiene than has typically been practiced in the past.[1,2]

Errors in exposure assessment decisions can damage both program effectiveness, because employee risks may have been underestimated and therefore not adequately managed, or program efficiency, because employee exposure risks may have been overestimated so resources may have been wasted on controls where none were needed.

Industrial Hygiene Program Management

The better the industrial hygienist understands exposures, the better he or she is able to direct and prioritize the industrial hygiene program. This is true whether the goal of the exposure assessment process is regulatory compliance, a comprehensive description of all exposures, or a diagnostic evaluation of health hazard controls. The system for exposure assessment must be integrated with other systems for defining, prioritizing, and managing worker health protection. Assessment results are used to determine the needs and priority for health hazard controls, build exposure histories, and demonstrate regulatory compliance.

Exposure assessment is at the heart of industrial hygiene programs as it provides the foundation for all of the functional elements (see Figure 1.1). A well-rationalized program relies on a thorough understanding of what is known — and not known — about exposures. For example, to understand where best to spend precious resources on a monitoring program, industrial hygienists must understand potential exposures that need better characterization or careful routine tracking. A thorough characterization of exposures allows the industrial hygienist to focus worker training programs, better target medical surveillance programs, and define specific requirements for personal protective equipment (PPE).

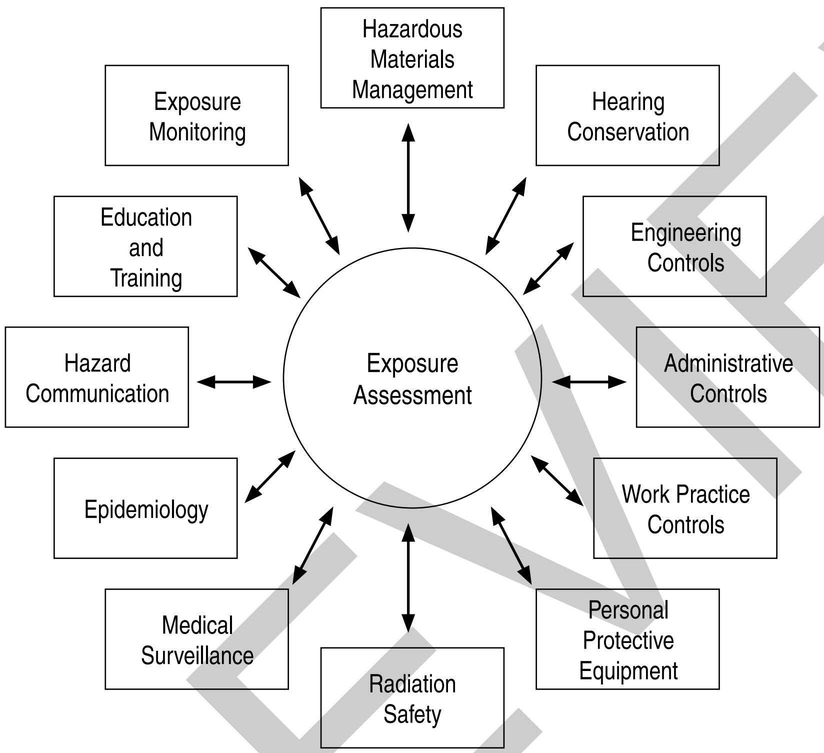


Figure 1.1 – Exposure assessment's central role in industrial hygiene program management.

Better Prioritization of Control Efforts and Expenditures

The better the understanding of exposures and the risks they pose, the more assurances there are that the most important (highest risk) exposures are being controlled first. Control efforts (whether engineering, work practice, or PPE programs) are often costly to implement and maintain. It is therefore critical that those efforts be appropriately prioritized, deployed, and managed.

A thorough understanding of exposures allows prioritization of control efforts to use limited funds wisely. The right combination of control efforts — including short- term, long-term, temporary, and permanent controls — can be implemented based on the prioritized exposure assessments. Plans can be made for improving controls and moving from short-term solutions such as personal protective equipment to long-term solutions such as local exhaust ventilation. Management will be assured that money is being spent first on the controls needed most and not wasted on unnecessary control efforts.(3)

Better Understanding of Worker Exposures

A full understanding of exposures, combined with work history, allows for better characterization of individual worker exposures and better management of employee medical concerns. The management of issues related to public health in the community in which the organization operates may be enhanced if there is a well-developed understanding of occupational exposures. Exposure histories, along with health effects information, can indicate the risk a person or group of people has of developing an occupational illness or disease. By understanding exposures, medical practitioners can better target clinical examinations, medical surveillance, or other diagnostic techniques to detect health effects early. When combined with individual medical histories, a comprehensive characterization of exposures greatly improves the power of epidemiological studies and better positions health care providers to answer questions about an individual's exposures and how they might have affected his or her health.

Exposure Assessment vs. Risk Assessment

For the industrial hygienist, exposure assessment and risk assessment are inextricably mixed such that they cannot be reasonably separated. Consider the following relationship between health risk and exposure:

Health Risk = (Exposure)(Toxicity)

In the world of industrial hygiene, evaluation of exposure is fully half the assessment of health risk. The other half is evaluation of the health effects per unit exposure, or the toxicity of the agent to which the worker is exposed. Thus, any exposure in an industrial hygiene sense is only meaningful in its relationship to the health effects the exposure might cause.

This book will not go into detail on the evaluation of agent toxicity. It is mentioned here, however, to highlight the important connection and interaction between the toxicity and the exposure in eventually determining the health risk.

The industrial hygienist's ultimate goal is to provide reasonable assurance of worker health. In this regard, what one does about risk is called risk management. Control of health hazards can be considered a risk management function. Here again, there is interaction with risk assessment in that good risk management is almost always predicated on good risk assessment, which in turn is driven by the quality of the industrial hygienist's exposure assessments.[4–6]

State of the Art: Comprehensive Exposure Assessment

In the past several years, characterization of exposures has received the attention of occupational hygiene professionals and regulatory agencies worldwide.[7–12] The state-of-the-art approach has shifted from compliance monitoring, which focuses on the maximum-risk employee to determine whether exposures are above or below established limits, to comprehensive exposure assessment, which emphasizes characterization of all exposures for all workers on all days.

Regulations in many countries now mandate some periodic review of exposures throughout an organization.[13–15] Although current regulations vary widely in scope and enforcement, the trend is clear — and the reasoning behind the trend indisputable: A comprehensive approach to assessing occupational exposures better positions an organization to understand the risks associated with the exposures and better positions the organization to manage those risks.

No longer is a compliance-based approach to industrial hygiene the primary focus of the profession. If industrial hygienists accept a broadened definition of risk and agree that their customers — workers and the organizations that employ them — are looking to them to help manage those risks, they will come to the conclusion that industrial hygiene practice must embrace a comprehensive and systematic approach to the evaluation of exposures and the risks they pose. This approach will include logical systems and strategies for evaluating all exposures, interpreting and assessing the many present and future risks those exposures might pose, and efficiently managing those exposures that present unacceptable risks.

Overview of Exposure Assessment Strategy

An overview of the exposure assessment strategy discussed in this text is shown in Figure 1.2. The strategy is cyclic in nature and is used most effectively in an iterative manner that strives for continuous improvement. Early cycles will begin by collecting available information that is relatively easy to obtain. The results of initial exposure assessments based on that information will be used to prioritize follow-up control and information-gathering efforts. Resources should be focused on those exposures with the highest priority based on the potential health risk they present. As those exposures are better understood and controlled, they will drop in priority and the next cycles through the strategy will focus on the next tier priority exposures.

The major steps in the strategy are:

1. *Start:* Establish the exposure assessment strategy – including the definition of decision criteria for acceptable exposures.
2. *Basic Characterization:* Gather information to characterize the workplace, work force, and environmental agents.
3. *Exposure Assessment:* Assess exposures in the workplace in view of the information available on the workplace, work force, and environmental agents. The assessment outcomes include a) groupings of workers having similar exposures; b) definition of an exposure profile for each group of similarly exposed workers relative to the appropriate OEL; and c) judgments about the acceptability of each exposure profile.
4. *Further Information Gathering:* Implement prioritized exposure monitoring or the collection of more information on health effects so that uncertain exposure judgments can be resolved with higher confidence.
5. *Health Hazard Control:* Implement prioritized control strategies for unacceptable exposures.
6. *Reassessment:* Periodically perform a comprehensive re-evaluation of exposures. Determine whether routine monitoring is required to verify that acceptable exposures remain acceptable.
7. *Communications and Documentation:* Although there is no element in Figure 1.2 for "communications and documentation," the communication of exposure assessment findings and the maintenance of exposure assessment data are assumed throughout as essential features of an effective process.

Management and Exposure Control Categories		
	SEG Exposure Control Category**	Applicable Management/ Controls
	0 (<1% of OEL)	no action
	1 (<10% of OEL)	procedures and training, general hazard communication
	2 (10-50% of OEL)	+ chemical specific hazard communication, periodic exposure monitoring
	3 (50-100% of OEL)	+ required exposure monitoring, workplace inspections to verify work practice controls, medical surveillance, biological monitoring
	4+ (>100% of OEL, Multiples of OEL; e.g., based on respirator APFs)	+ implement hierarchy of controls, monitoring to validate respirator protection factor selection
***Upper Tail Statistic decision = 90th, 95th, 99th percentile*		

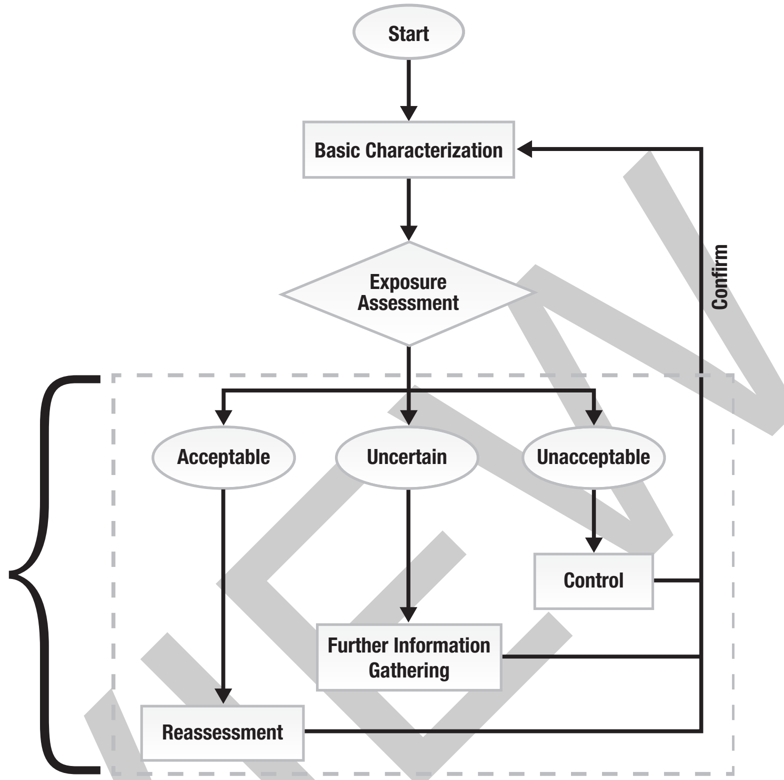


Figure 1.2 – A Strategy for assessing and managing occupational exposures.

The following paragraphs describe each of the seven steps:

1. Start: Establish the Exposure Assessment Strategy

In establishing an organization's exposure assessment strategy, the following issues should be carefully addressed:

- Role of the industrial hygienist;
- Exposure assessment goals;
- Decision criteria for determining whether an exposure is acceptable, and
- Written exposure assessment program.

2. Basic Characterization

Begin the exposure assessment process by collecting and organizing basic information needed to characterize the workplace, work force, and environmental agents. Gather information that will be used to understand the tasks being performed, materials being used, processes being run, and controls in place so that a picture of exposure conditions can be made.

6

Approaches to Improving Professional Judgment Accuracy

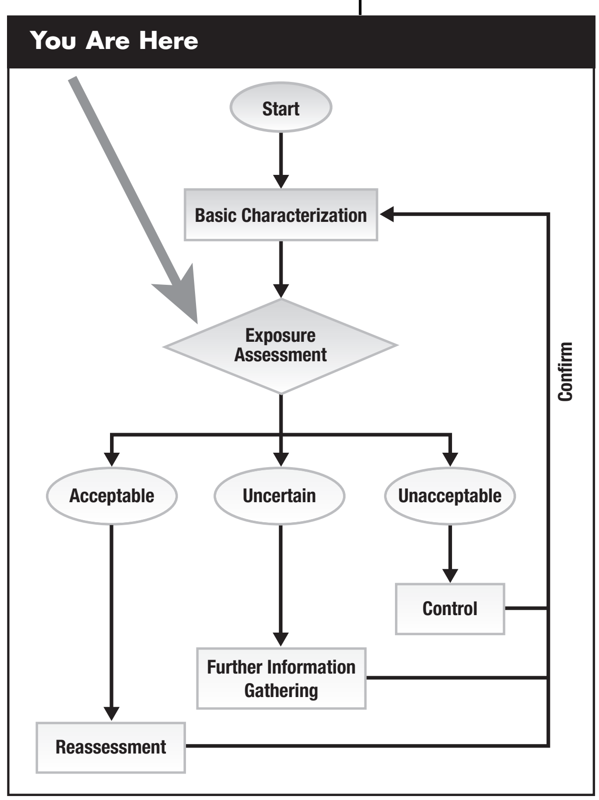
By Susan Arnold, CIH, FAIHA, Mark Stenzel, CIH, FAIHA, and Gurumurthy Ramachandran, PhD, CIH, FAIHA

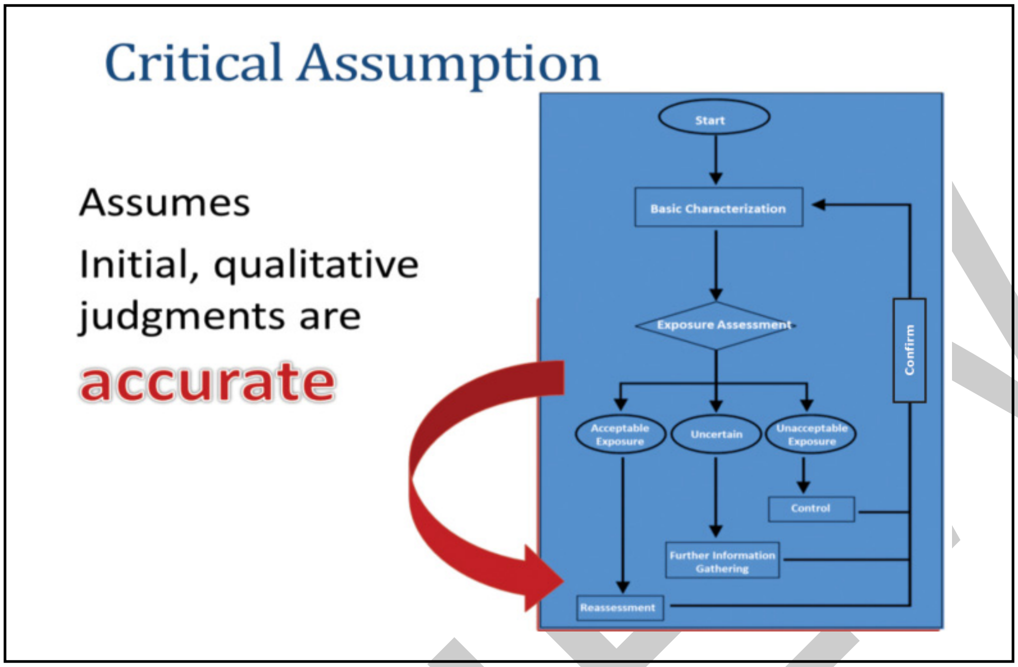
Introduction

Professional judgment plays a critical role in any field in which decisions must be made in the absence of a complete data set. Medical professionals, weather forecasters, financial analysts, and industrial hygienists all use professional judgment to facilitate decision making. Professional judgment, defined as "the application and appropriate use of knowledge gained from formal education, experience, experimentation, inference and analogy that reflects the capacity of an experienced professional to draw correct inferences from incomplete quantitative data, frequently on the basis of observations, analogy and intuition."[1,2] In short, it ensures that in the face of uncertainty, inputs to decision making are considered and weighted appropriately.

When following a comprehensive exposure assessment strategy such as the AIHA's Exposure Assessment Strategy (the Strategy outlined in this text, Chapters 1 through 11), hygienists assess all exposures, to all chemicals, for all workers. Implementation of such a strategy typically occurs at the task-level during all shifts (combination of tasks worked at various frequencies and durations in completing worker job responsibilities), resulting in tens, if not hundreds of thousands of exposure scenarios. The AIHA® Strategy provides an elegant and efficient framework for systematically evaluating all of them. There is a caveat: the strategy assumes that qualitative and quantitative exposure judgments are reasonably accurate.

Exposure judgments are used in a wide range of situations, including retrospective exposure assessments for epidemiology studies[3-6] and current as well as





prospective exposure assessments for managing exposures related to consumer use and manufacturing operations.[7-10] When there are limited or no sampling data available, industrial hygienists (IHs) use a combination of professional judgment, personal experience with a given operation, and review of exposures from similar operations to assess the acceptability of exposures for managing engineering controls, medical surveillance, hazard communication and personal protective equipment programs.[6,8,11-17] In many cases, there is not an opportunity to collect quantitative measurements prior to making an exposure assessment judgment. For example, hazard communication triggered by an exposure assessment must be made prior to the introduction of the agent into the workplaces; similarly, a theoretical technical basis is often the only thing available to define adequate engineering controls related to the introduction of new processes or changes in existing processes.

We use the term "qualitative" to describe judgments or decisions made in the absence of quantitative personal exposure data. This term is further subdivided in our discussion according to the type of inputs from which the judgments are synthesized; subjective qualitative judgments are based on intuition or 'personal experience' that is not overtly defined. Objective qualitative judgments are produced using structured approaches.

In the context of this chapter, a decision is represented by a chart showing the hygienist's assessment of the probabilities that the 95th percentile lies in each of the four categories (Figure 6.1).

The Strategy directs hygienists to conduct initial, qualitative screening assessments to identify those Category 1, 2 or 3 exposures that are clearly acceptable, (i.e. X0.95 < 10% OEL up to X0.95 < 100% OEL) or Category 4 exposures deemed unacceptable, (i.e. X0.95 > OEL). These initial judgments may be based on objective strategies such as exposure modeling, or checklists or (more typically) on subjective intuitive approaches. Since the outcome of these initial judgments determine what initial controls and type of follow up, if any, occurs, making accurate qualitative judgments is paramount. Further, since preventing over-exposures and realizing the Strategy's efficiency occurs when resources are focused on those scenarios truly needing follow up, accurate quantitative exposure judgments are equally critical.

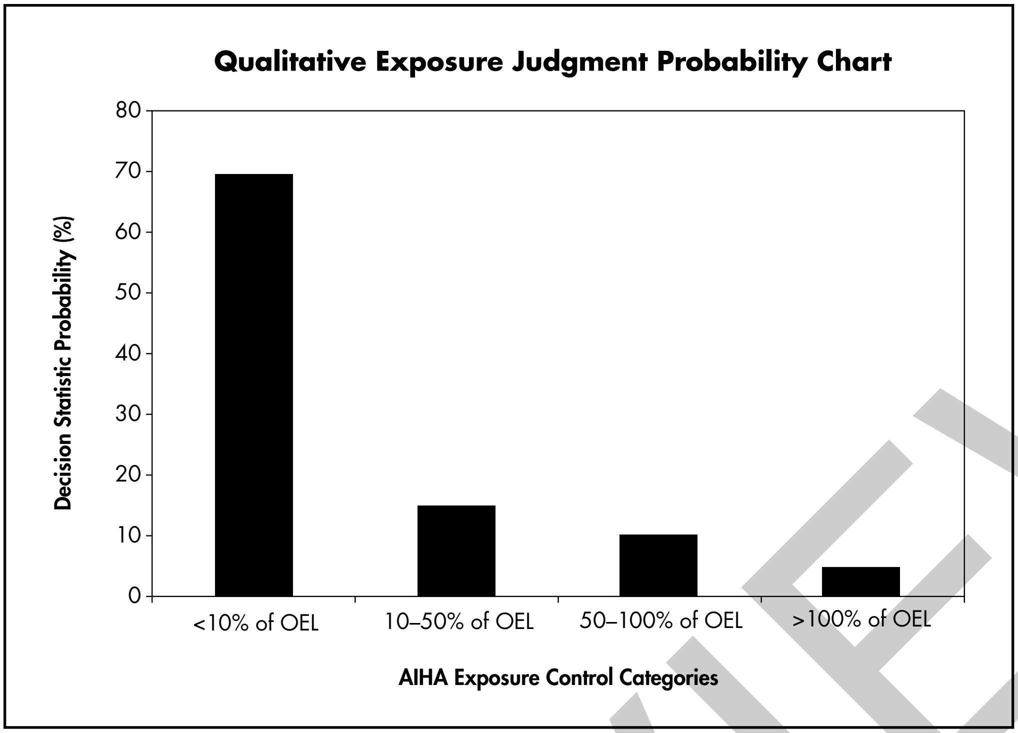


Figure 6.1 – Example qualitative exposure judgment chart illustrating an occupational hygienist's exposure judgment given the information and data available. This chart shows the hygienist's assessment of the probabilities that the 95th percentile falls into each of the four AIHA® Exposure Categories.[14]

Approaches to Decision Making

Subjective judgments focus on the scenario, with each case being treated as if it were unique. They are based on intuition, defined as "the situation has provided a cue; this cue has given the expert access to information stored in memory and the information provides the answer. In short, it is nothing more and nothing less than recognition."[18] Subjective judgments tend to be less structured, considering the information provided from the basic characterization and relying on information that is easily retrievable from memory, experience with situations deemed similar (to the scenario being assessed), and various other inputs. "Intuition can be a useful tool aiding in accurate decision making if, and only if it is followed by the disciplined collection of objective information with disciplined scoring and analysis of that information. In other words, intuitive judgments can be useful when delivered by well-calibrated, experienced professionals operating within their domain of expertise."[18]

Subjective methods for decision making range from the less transparent intuitive approach, to the more disciplined and systematic approaches. A more rigorous, systematic approach may be derived from careful reviews of available information about exposure agents and data related to the work force, jobs, materials, work practices, engineering controls and protective equipment. This is supplemented with worker interviews, review of the technical basis for exposure limits, and when available, personal monitoring data.

When do judgments reflect true expertise?

When the environment is sufficiently regular to be predictable AND the expert has had time and the opportunity to learn these regularities through practice AND the expert can express a judgment accurately in probabilistic terms.

Subjective judgments of exposures for complex scenarios tend to be inaccurate and inconsistent(19) (with the exception of theoretically extreme scenarios, such as those encountered in HAZard and OPerability Analysis [HAZOPs] situations, where one looks at the possible outcomes (worst case, likely case, etc.), considers layers of protection, numbers of people potentially affected, and arrives at a judgment in probabilistic terms). Moreover, assessments based on inadequate or poorly conducted basic characterization tend to be inaccurate and inconsistent.

In fact, research has shown subjective qualitative exposure judgments tend to be no more accurate than random chance, with a significant underestimation bias, i.e., there is marked tendency to assign a lower exposure category than the correct one, thus increasing occupational risk to workers.(14,16,17,19) Logan and Vadali examined qualitative and quantitative exposure judgment accuracy by soliciting exposure judgments for a range of exposure scenarios, initially without revealing personal exposure monitoring data to obtain qualitative judgments, and then presenting the data one data point at a time, with data sets ranging in sample size from n = 1to 8, thus obtaining quantitative judgments. To ensure that a highly confident Reference Exposure Control Category could be computed, only those exposure scenarios with a robust data set of personal exposure data were included in the study. IHs indicated which of the four exposure control categories they believed the 95th percentile of the exposure distribution belonged. Exposure judgments were deemed accurate if the Predicted Exposure Control Category (a "professional judgment") matched the Reference Exposure Control Category.(14,16,19) Study participants were provided with videos of the scenarios(14) or able to visit the facility and observe the operation(16), and yet given basic characterization information including exposure determinant information (as well as given the opportunity to ask the investigators questions about the scenarios), there was little formal consideration of this information. Further, they did not follow any process for arriving at their judgments.

Studies also indicate exposure judgment accuracy of subjective quantitative judgments based on small data sets of personal exposure data (n <6) is also low (< 50%), though better than random chance(14,16), and they improve significantly following training on some simple data analysis rules.

The low accuracy could be due to several factors. Industrial hygienists receive little, if any formal training on how to conduct a basic characterization. If this step of the exposure assessment is not conducted in a systematic way, using physical and chemical principles, and collecting the relevant exposure determinant information, the hygienist may not investigate the exposure that presents the highest exposure potential with sufficient detail, leading to low judgment accuracy.

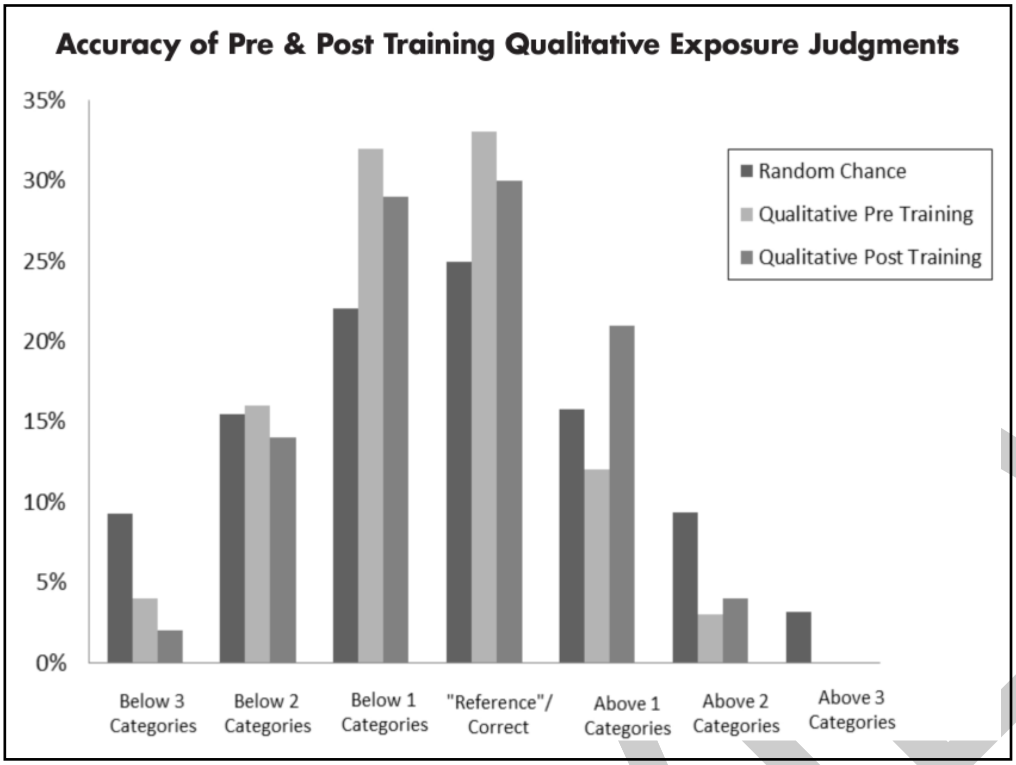


Figure 6.2 – Percentage of pre and post-training qualitative task judgments categorically correct, above and below reference categories in a desktop study, N = 3834.[14] In this case, the differences were not statistically significant.

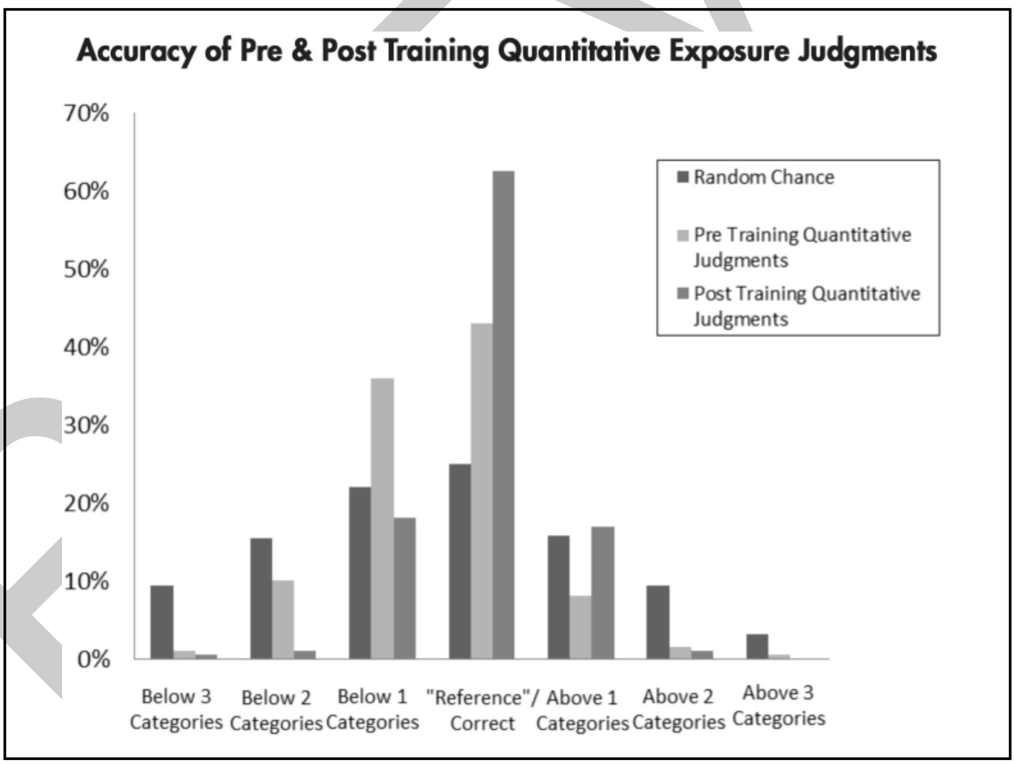


Figure 6.3 – Percentage of pre and post-training quantitative task judgments categorically correct, above and below reference categories in a desktop study, N = 3834.[14]

14

Noise Stressors

By Lee Hager and Carl Johnson, MS, CIH

Exposure to excessive noise can pose a risk to human health. Most commonly and of greatest interest, exposure to excessive noise may result in permanent damage to hearing. In addition, some research implicates noise exposure in a range of other stress-related health effects, including hypertension, sleep disturbances, and more.(1)

Excessive noise is a common workplace exposure hazard, affecting up to 30 million workers in the U.S. alone.(2) According to the Bureau of Labor Statistics, occupational hearing loss is the second most commonly recorded occupational illness and occupational exposure to noise is implicated in over 200,000 cases of permanent hearing impairments since 2004.(3) Noise-induced hearing loss is the most common occupational illness in North America, and noise is a factor in up to 10 million cases of hearing loss in the U.S.

Assessing Risk of Hearing Impairment

Noise is defined by intensity (measured in decibels or dB) and frequency (measured in cycles per second and expressed as hertz or Hz). The decibel is a dimensionless unit of pressure and is logarithmic. Each doubling of pressure yields an increase of 6 dB in sound pressure level (SPL). Material risk to human hearing is typically thought to begin with long-term (i.e., 40-year work life) exposure to sounds approaching or exceeding 85 dB, as reflected in Table 14.1.

Noise frequency, the second component which defines noise, is expressed as hertz (hz), and is composed of spectral or tonal characteristics. Human hearing can detect sounds from about 20 to about 20,000 hz, with noise-induced hearing loss (NIHL) typically manifesting in the range of about 2000 to 6000 hz.

As with most workplace hazards, the permissible level of exposure to noise is negotiated among rulemakers and defined in pertinent laws and regulation. With noise, however, it is important to consider that the exposure permitted under regulatory statutes may result in increased prevalence of noise induced hearing loss than some may find unacceptable.

Table 14.1 – Noise-related Damage Risk Criteria

Percent risk of material hearing loss (hearing threshold levels >= 25 dB) above that anticipated in non-noise exposed population, based on 40-year working lifetime.

Organization	*Exposure Level dB(A)*	*% Excess Risk of Material Hearing Impairment*
ISO (1975)	90	21
	85	10
	80	0
EPA (1973)	90	22
	85	12
	80	5
NIOSH (1972)	90	29
	85	15
	80	3

Note that the studies cited in the table date from the 1970s. While widespread introduction and use of hearing protection devices (HPD) have made this type of risk assessment more difficult, reanalysis of older data and some newer studies confirm these general values.[4]

Another way to view risk assessment is through the Exposure Rating Categorization protocol described elsewhere in this manual. For the purposes of noise exposure evaluation, eight-hour TWA (TWA8) and percent dose are correlated to exposure rating in the table here. If using a criterion level or exchange rate other than 90 and 5, the exposure categories remain the same in terms of the percent of the occupational limit/percent dose, but the corresponding TWA 8 would change.

Table 14.2 – Noise SEG Exposure Control Categories

TWA8 and Noise Dose	*SEG Exposure Control Category***	*Applicable Management/ Controls*
<56.8 dBA <1%	**0** (<1% of OEL)	Hearing loss prevention awareness training optional
56.8–73.4dBA 11-10%	**1** (<10% of OEL)	Hearing loss prevention awareness training optional
73.4–85 dBA 10-50%	**2** (10–50% of OEL)	+ Hearing loss prevention awareness training, periodic exposure monitoring
85–90 dBA 50-100%	**3** (50–100% of OEL)	+Hearing Conservation Program inclusion, exposure monitoring, medical surveillance, PPE requirements begin, consider hierarchy of controls
90–101.6dBA 100-500%	**4** (>100% of OEL)	+Implement hierarchy of controls, implement engineering controls
>101.65dBA >500%	**5** (Multiples of OEL)	+ Implement hierarchy of controls, validation of hearing protection sufficiency, dual HPD, priority engineering control

While exposure above 101.65 dBA TWA is included as category 5 in this estimation, there are significant questions as to the effectiveness of HPD at exposures above that level. Most agencies recommend or require dual hearing protection (earmuffs over earplugs) for these exposures[5,6] and extra emphasis on control.

Basic Characterization – Workplace and Work Force Characterization

Effective management of noise and hearing loss prevention in the workplace starts with a thorough understanding of noise sources and exposures.

Basic workplace characterization should start with a thorough "walk-around" noise survey intended to identify and inventory predominant noise sources and tasks with significant noise exposure. In addition to fixed equipment, mobile noise sources such as air hoses and noisy hand tools should be identified. Evidence of potential for significant intermittent exposure such as elevated part bins (indicating the potential for occasional part dumping), metal work tables or surfaces or pneumatic tools such as impact wrenches or grinders should be noted for further investigation.

Interviews with supervisory and production personnel should focus on ensuring that the noise source inventory is complete, that noise controls which are in place are identified and functioning as designed, and that off-shift, seasonal, and intermittent noise sources are identified. Basic workplace characterization should identify predominant noise sources and initial determination of worker interaction with noise sources to help prioritize quantitative measurement activity.

Work force characterization should be conducted in a manner similar to other exposure assessments:

- Use of existing personnel organizational infrastructure such as departments, job functions, groups, teams, cells and job classifications as primary data organization template is highly recommended.
- Care should be taken to identify the potential for worker mobility, both physical and organizational. Transient workers such as maintenance staff may work in various areas of the plant, but some production workers may work across department or team lines as well. Both types of mobility are important for risk assessment. The variability of the work associated with this type of process can make it difficult to conduct a comprehensive exposure assessment. By developing an understanding of both the temporal and spatial changes, the best estimate of the exposure can be derived.
- Noise exposure may be a function of location proximal to a noise source, activity that creates noise or a combination of these effects. Both routes of exposure must be identified as risk is assessed.
- As with chemical exposure assessment, identification of similar exposure groups is critical. By carefully considering the people, equipment, tasks, and materials, the practicing hygienist can effectively identify the groups of workers with similar exposures.

Initial determination and documentation of exposure risk for all SEGs, even those with minimal risk of exposure, is recommended. This process will build a longitudinal record of sources and personnel exposures that may be of value in determining work-relatedness of hearing loss for recordability or compensation purposes, and can provide a baseline for comparison with future conditions and activity.

Qualitative Exposure Assessment

Qualitative exposure assessment of general noise levels can be relatively simple. If you are standing in a noisy environment, must you raise your voice to be heard at arm's length from the listener? This phenomenon typically occurs as background sound levels approach or exceed 85 dB, the most commonly used threshold of risk. Qualitative exposure assessment can be more complex in situations where

25 Occupational Exposure and Control Banding

By Bernard D. Silverstein, MS, CIH, Susan Ripple, MS, CIH, and Donna S. Heidel, MS, CIH

An Overview of Occupational Exposure and Control Banding

Occupational Exposure and Control Banding (OECB) is a concept for qualitative risk assessment and management of hazards in the absence of occupational exposure limits (OELs). It is recognized that the development of authoritative OELs, including Occupational Safety and Health Administration (OSHA) permissible exposure limits (PELs), the American Conference of Governmental Industrial Hygienists (ACGIH®) threshold limit values (TLV®), and the National Institute of Occupational Safety and Health (NIOSH) recommended exposure limits (RELs), will continue to be significantly outpaced by the introduction of new chemicals into commerce due to the data that needs to be analyzed to assure the accuracy of an authoritative OEL. However, industrial hygienists require guidance on how to assess exposure risks to chemical agents in the absence of an OEL. Occupational exposure banding or control banding fills this gap.

Indeed, OECB does facilitate our goal of protecting worker health by focusing our limited personnel and financial resources on exposure controls rather than the arduous process of quantitative risk assessments required for the establishment of authoritative OELs.[1]

Occupational Exposure Banding can serve as the first step in a comprehensive risk management approach to chemical hazards. OECB is arguably one of the most appropriate ways to group families of materials where data or resources are too limited to allow for a comprehensive and conclusive assessment of risk. Following qualitative or semi-quantitative exposure assessment, industrial hygienists can confidently develop exposure control strategies. Therefore, the OECB process will further expand the scope of Industrial Hygiene to all chemical hazards and will facilitate informed decision-making of the design of processes, products and facilities and will significantly achieve the goal of eliminating or substituting hazards and minimizing risks by specifying the appropriate engineering controls.

Figure 25.1 shows a comparison of the traditional industrial hygiene (IH) Process using Anticipation, Recognition, Evaluation, Control and Confirm in the green box aligned with the newer forms of Hazard Assessment, Exposure Risk Assessment and Exposure Management.[2] The Hazard Assessment process drives identification and definition of the 'hazard criteria' such as OEBs and OELs, and notations. While traditional industrial hygienists would have struggled with the process in the absence of an OEL, new opportunities to further define the hazards are available with the use of OEBs. Exposure Risk Assessment compares the relevant exposure information against the hazard criteria allowing hygienists to define controls and programs utilizing a hierarchy of controls approach. This approach expands the capabilities of the industrial hygiene process to evaluate a broader array of chemicals in the workplace using Hazard and Control Banding strategies.

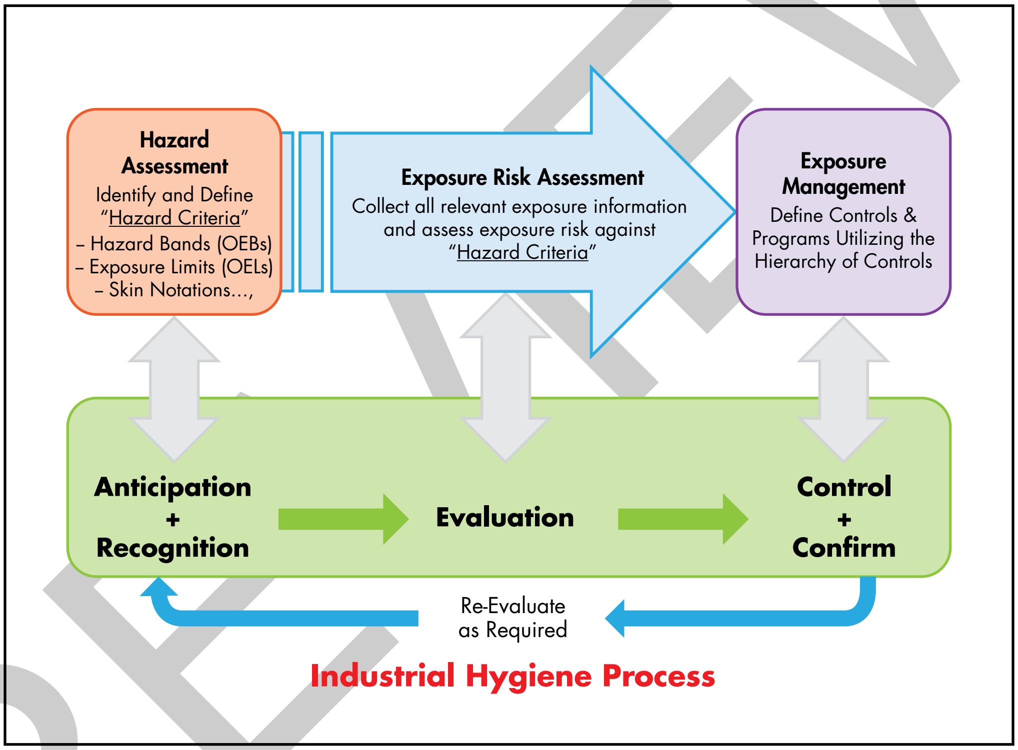


Figure 25.1 – Comparison of Exposure Assessment Framework[2]

Pharmaceutical Approach

In the U.S., Control Banding was initially proposed and implemented in the late 1980s by the pharmaceutical industry to provide guidance on effective exposure control approaches to Industrial Hygienists supporting the development and synthesis of novel, high-potency, receptor-mediated, active pharmaceutical ingredients (API) without no-effect levels used to establish an OEL. When OELs in the low microgram or even nanogram per cubic meter ranges were proposed, there was limited knowledge about how to accurately assess worker exposure risks since industrial hygiene analytical methods to measure task-based exposures to these APIs, at the very low concentrations that were required, were just being developed. Therefore, a new method for ensuring the occupational health of workers involved in producing these APIs, as well as to the laboratory scientists discovering and developing investigational new drugs, was needed. The industry recognized that, despite the broad range of OELs that were developed for APIs, the task-based exposure controls, both in the laboratory as well as in production, were grouped together in up to 5 different groups. Therefore, the original Control Banding approach linked the known or potential hazards of a novel investigational new drug or API to a suite of controls that were deemed effective in managing worker exposure risks. Using the approaches adopted to control worker exposure to biohazards, as outlined in *Biosafety in Microbiological and Biomedical Laboratories*, the industry developed a model for control bands for these high potency molecules.[3,4]

The pharmaceutical industry occupational toxicologists and Industrial Hygienists were successful in supporting the safe development and commercialization of these novel new drug products. Their efforts also drove the development and widespread adoption of advanced engineering containment techniques, supporting the application of the industrial hygiene hierarchy of controls.

COSHH Essentials

The concept of OECB was implemented as a strategy to assess hazards and control exposure risks in the workplace within the United Kingdom during the late 1980s. The Control of Substances Hazardous to Health (COSHH) regulations were developed to address the realization that development of OELs for all of the chemicals in commerce would not be cost effective, limiting new OELs to widely used substances of concern.[5]

Hazard Banding

Exposure or Health Hazard Banding (HB) is simply the first step of the traditional ‘Control Banding’ (CB) process. Decoupling HB from the CB process allows hazard assessment to then serve as a utility in hazard communication and awareness efforts after a substance has been introduced in a workplace.[6] The hazard assessment can aid in the substitution or prevention of exposure through the design of controls. Although HB is not a substitute for OELs, HB yields insight into the relative toxicity of substances. Industrial Hygienists can use this information to provide expert guidance for hazard ranking and prioritization.

Hierarchy of Occupational Exposure Limits

Hazard or Occupational Exposure Bands (OEB) are one tool that hygienists can use in the “Hierarchy of OELs” (Figure 25.2) when forming a comparison or relative ranking between substances for substitution decisions, or when determining the relative “Hierarchy of Controls” needed for a process.[6] Occupational Exposure Bands can be set with relatively little data, but OEBs are also regularly set with robust datasets, containing human health and animal toxicity data, when an official OEL is not needed. Either way, the OEB is a helpful tool in performing the qualitative exposure risk assessments when no other guidance exists.

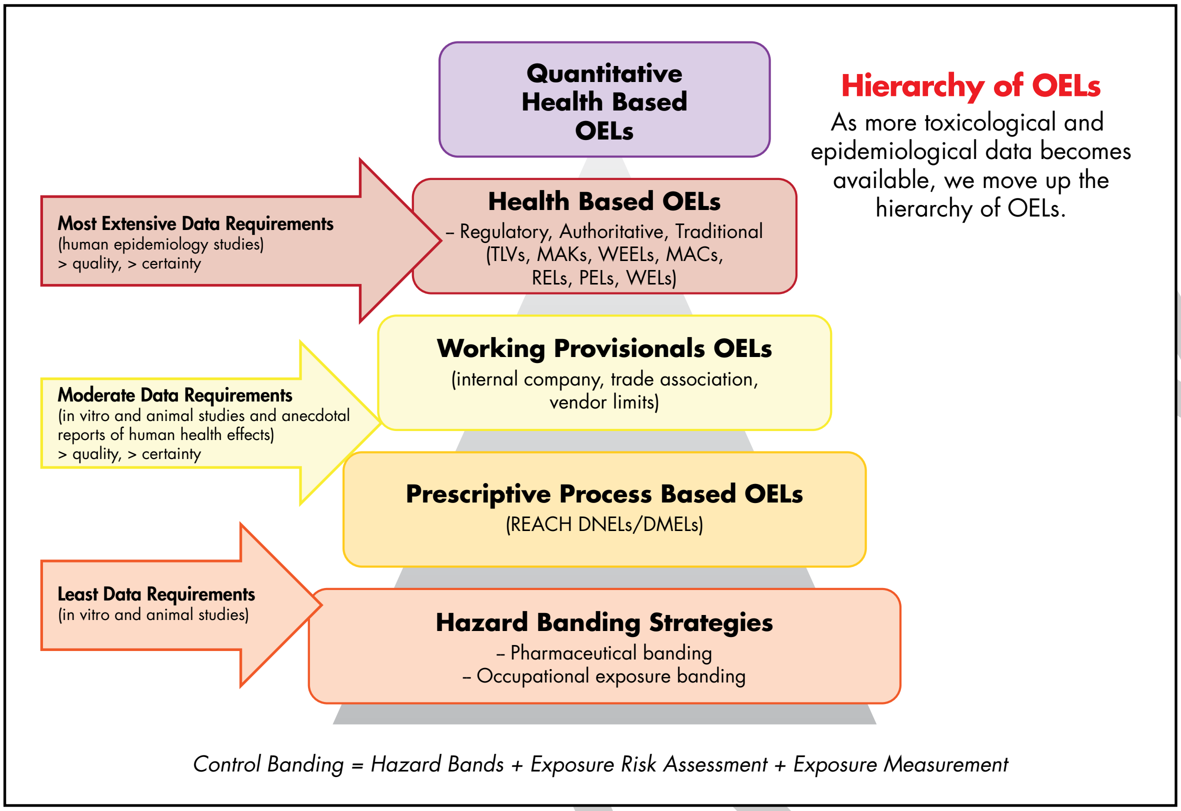


Figure 25.2 – Hierarchy of OELs. (AIHA Taskforce 2012)

In general, allocation of substances into hazard bands is influenced by the presence of an identifiable technical source, seriousness of the resultant health effect, and relative exposure level at which toxic effects occur. The European Economic Committee (EEC) in the "classification, labelling and packaging of substances and mixtures" directive[7], designated Risk Phrases (R-Phrases) and subsequently modified them to Health Phrases (H-Phrases)[8] to identify the hazards from hazardous workplace exposures. This 2008 change in Europe provides for a better alignment with the GHS system. Hazard is generally described in terms of the toxicologic endpoint of concern (e.g., the description associated with specific R-phrases). Such phrases give the critical endpoints of disease. Where additional toxicologic data exist, they can be used for further assessment of the hazard ranking methodology. The R or H phrase depicting the highest level of toxicity is used to determine the Hazard Band.

For this discussion, Hazard Banding strictly refers to "Health Hazard Banding" and does not include the often controversial qualitative exposure assessments (risk characterization) performed in CB, nor does it touch on the predicted control strategies that might be used to perform Risk Management in CB. However, once the Hazard Banding process has been completed, the Industrial Hygienist can determine the risk assessment and control strategies, thereby completing the IH process. Hazard Banding does not replace industrial hygiene expertise—specific operating knowledge and professional judgment are required for implementation of the best "reasonably practicable" combination of controls to minimize risks to workers. Hazard Bands for a chemical provide a range of acceptable exposure levels based on expert evaluation of the dose-response relationships provided through animal testing. HB provides a mechanism for the evaluation of hazard and risk to offset the misconceptions by employers and workers that a substance must be non-toxic if there is not an OEL.[9]

Appendix IV

Descriptive Statistics, Inferential Statistics, and Goodness of Fit

By John Mulhausen, PhD, CIH, CSP, FAIHA and Sheryl Milz, PhD, CIH

Statistics are necessary when evaluating workplace exposures. The AIHA® strategy focuses on the statistical evaluation on the upper tail of the exposure profile (e.g., the 95th percentile and the upper tolerance limit). This appendix provides a brief description of how to calculate the statistics that can be used to help make a decision on the acceptability of exposures.

Descriptive Statistics

Descriptive statistics are used to summarize data. These statistics include measures of central tendency (e.g., mean, geometric mean, minimum variance unbiased estimate of the mean) and measures of dispersion or spread (e.g., minimum and maximum, range, standard deviation, and geometric standard deviation).

Descriptive statistics help to organize monitoring data in order to begin understanding the exposures the monitoring data represent. While monitoring data may be interpreted just by comparing the calculated descriptive statistics with the OEL, such as when all of the monitoring data are clustered well below (<10%) or well above the OEL, as a rule, inferential statistics should always be calculated to aid the decision making. In particular, if the monitoring data are near or include the OEL, inferential statistics, such as the 95th percentile and its confidence intervals, must always be calculated to aid in decision making. Modern software programs, including readily available freeware programs like IHSTAT and IH DataAnalyst–Lite Edition (IHDA-LE), allow the industrial hygienist to easily calculate descriptive and inferential statistics. Both freeware programs include the descriptive and inferential statistics discussed in this appendix.

The following descriptive statistics should be routinely calculated for all monitoring data:

- number of samples (n)
- maximum exposure (max)
- minimum exposure (min)
- range
- percent of exposures greater than OEL (%>OEL)

- mean exposure ($\bar{x}$)
- standard deviation of exposures (s)
- mean of log-transformed exposures ($\bar{y}$)
- standard deviation of log-transformed exposures (s_y)
- geometric mean (GM)
- geometric standard deviation (GSD)

Additionally, plotting the monitoring data over time (earliest samples first) in a simple sequential plot may be useful. This plot can indicate trends, either increasing or decreasing, in exposures over time (non-stationary distribution).

Calculating Descriptive Statistics

Using the monitoring data in Table IV.1, the above listed descriptive statistics and the sequential plot will be demonstrated. (NOTE: Using a computer spreadsheet or statistical software may produce different answers than those printed in this section due to rounding differences). Table IV.1 includes the exposure data in the order it was collected, along with the intermediate values needed to calculate the descriptive statistics of interest. All of these descriptive statistics are included in the calculations available in IHSTAT and IHDA-LE.

Table IV.1 – Example Data (OEL = 5 mg/m³)

Sample Number	x_i *Monitoring Data (mg/m³)*	$(x_i - \bar{x})^2$	$y_i = ln(x_i)$ *Log-transformed data*	$(y_i - \bar{y})^2$
1	1.3	1.904	0.262364	0.416725
2	1.8	0.774	0.587787	0.102477
3	1.2	2.190	0.182322	0.526473
4	4.5	3.312	1.504077	0.355420
5	2.0	0.462	0.693147	0.046122
6	2.1	0.336	0.741937	0.027546
7	5.5	7.952	1.704748	0.634957
8	2.2	0.230	0.788457	0.014268
9	3.0	0.102	1.098612	0.036369
10	2.4	0.078	0.875469	0.001052
11	2.5	0.032	0.916291	0.000070
12	2.5	0.032	0.916291	0.000070
13	3.5	0.672	1.252763	0.118926
14	2.8	0.014	1.029619	0.014814
15	2.9	0.048	1.064711	0.024588
	$\sum x_i =$ 40.2 *mg/m³*	$\sum (x_i - \bar{x})^2 =$ 18.14	$\sum y_i =$ 13.62	$\sum (y_i - \bar{y})^2 =$ 2.320

Sequential Plot

Figure IV.1 displays the simple sequential plot of the exposure data with sample number on the x-axis and concentration on the y-axis.

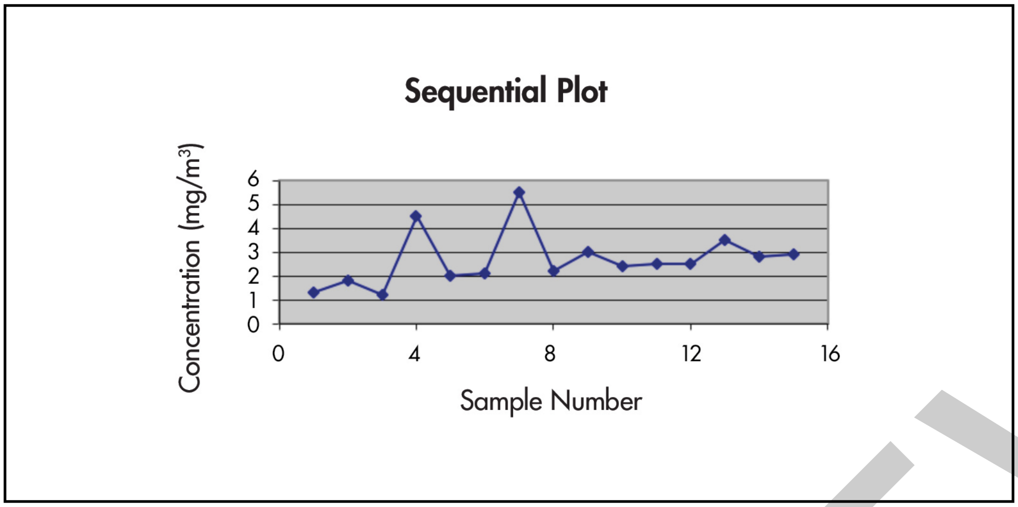


Figure IV.1 – Sequential Plot

Number of Samples

The number of samples (n) can be determined through observation.

$n = 15$

Minimum Exposure

The minimum exposure (min) can be determined through observation.

$\text{min} = 1.2\ mg/m^3$

Maximum Exposure

The maximum exposure (max) can be determined through observation.

$\text{max} = 5.5\ mg/m^3$

Range

The range is calculated by subtracting the minimum exposure from the maximum exposure.

$$range = \text{min - max} \qquad \text{(IV.1)}$$

$$range = 5.5\ mg/m^3 - 1.2\ mg/m^3 = 4.3\ mg/m^3$$

Percent of Exposures Greater than the OEL

The percent of exposures greater than the OEL (%>OEL) is calculated by dividing the number of samples greater than the OEL by the total number of samples and multiplying by 100. This is a nonparametric statistic.

$$\%\ > OEL = \frac{number\ of\ samples > OEL}{total\ number\ of\ samples} * 100 \qquad \text{(IV.2)}$$

$$\%\ > OEL = \frac{1}{15} * 100$$

$$\%\ > OEL = 6.7\%$$

A Strategy for Assessing and Managing Occupational Exposures, 4th edition

Edited by Steven D. Jahn, CIH, MBA, William H. Bullock, DHSc, CIH, CSP, FAIHA and Joselito S. Ignacio, CIH, CSP, MPH, REHS/RS

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