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Permissible Exposure Limits (PELs)

White Paper

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Sponsored by the AIHA® Exposure Assessment Strategies Committee

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The focus of this white paper is the regulatory permissible exposure limits (PELs) for airborne chemicals as promulgated by OSHA. However, recognizing that OSHA has not been able to define up-to-date PELs for every chemical of concern in the workplace, these comments go further to suggest what employers and industrial hygienists may do to bridge the gap between the number of chemicals in use and the tools to define risk when PELs are not available. The AIHA Board of Directors originally adopted this white paper in 1998 and subsequently updated it in 2002, 2009, and 2015.

1. Exposure limits such as OSHA's PELs are a primary tool in disease prevention and are an essential part of a comprehensive occupational safety and health program.

The concept of the use of exposure limits as a means of protecting worker health has evolved from the industrial hygiene community's 60-plus years of experience[1] in developing and using such limits. maximum allowable concentrations (MACs), Threshold Limit Values (TLVs®), workplace environmental exposure levels (WEELs™), recommended exposure limits (RELs), and industry-developed occupational exposure limits (OELs) have been essential tools of the practicing industrial hygienist. While the goals, where stated, may differ[2] (e.g., to limit occupational cancer to 1 case in 1000 exposed workers over a working lifetime or to protect "nearly all workers"), these exposure limits are all designed to reduce the occurrence of worker illness or impairment resulting from exposure to chemicals.

The use of exposure limits to prevent occupationally related illness has been an effective tool used by industrial hygienists for more than six decades. AIHA recognizes the controversies that are often involved in the setting of these limits both in the regulatory and voluntary arenas. In developing PELs, the major concerns include scientific soundness, feasibility, timeliness, documentation, and opportunity for involvement of affected parties in the decision-making process.

We believe that when these considerations are a part of the exposure limit-setting process, and when the limits are applied as part of a comprehensive occupational health and safety program, they are a primary tool in disease prevention.

2. OSHA should seek whatever resources or legislative changes are needed to allow the updating of all existing PELs to current science and to set such new PELs as necessary to protect worker health. In the meantime, OSHA should select chemicals for PELs based on scientific principles, risk determinations, and specific criteria developed with all stakeholders.

Leverage Existing Scientific Data

It is a disservice to worker health that the majority of OSHA PELs are based on recommendations that were made more than 45 years ago (i.e., ACGIH's 1968 TLVs®). OSHA should review and update the PELs on a regular (three-to five-year) cycle, considering that recommended exposure limits, or RELs (NIOSH), TLVs® (ACGIH), workplace environmental exposure levels, or WEELs (Occupational Alliance for Risk Science), and other appropriate national and international standards that are anchored by good science are reviewed and updated regularly.

The limits noted above undergo extensive technical reviews and follow a formal process for development, review, and approval of individual limits. While the procedures and rationales may differ, all these limits provide a scientifically sound starting point and foundation for the prompt and continued upgrade of the OSHA PELs. By starting with such a solid base, OSHA's historical record (new PELs for only about two dozen substances in more than 25 years, or roughly one per year) can be markedly improved and worker health protection thus enhanced.

Absent a regular review and update process, many more PELs will become out of date. Researchers and other professionals are constantly developing new information regarding toxicity at the molecular, organ, system, and whole-body levels. This information must be incorporated into the PEL update process. To make this periodic update more efficient, OSHA should leverage work undertaken by the professional groups previously identified, as well as those within the international community that have developed science-based values.

Burden of Proof

It is also critical that the burden-of-proof requirements for adopting PEL updates be more flexible than those in the present OSHA Act. The decision by the 11th Circuit Court (which resulted in the vacating of 428 PELs adopted in January 1989) suggests that OSHA follow the Administrative Procedures Act (to ensure adequate review and comment) and legislatively establish a "not arbitrary or capricious" criterion rather than a "substantial evidence on the record" criterion regarding adoption of PELs by the agency.

Other legislative approaches that provide a balance between adequate technical/scientific review and the requirements defined by legislation in the courts may well exist. A balance must be struck between the opportunity for the regulated community to review and provide input to a standard-setting process and the need to reduce the time period for regulatory action. The present criteria clearly need modification when one considers OSHA's limited accomplishments in this arena since 1970.

Priority of Chemicals Set

Given the difficulty OSHA has demonstrated in setting PEL standards, it is necessary to consider prioritizing chemicals for update considerations. It is unlikely that OSHA would attempt to review, and possibly change, all exposure limits simultaneously.

Paustenbach[3] voices the concerns of stakeholders in the PEL update. He articulates two points regarding priorities in the update of PELs.

> The prospect of a "list" of chemicals seems to bother everyone. To some extent, there is a general mistrust of any process wherein a certain chemical is targeted for regulation while another is not. One way to prevent this from being the focus of attack would be to drop the list entirely. Instead, the Agency might

> present a generic formula for different toxicological effects for calculating "preliminary" PELs for various classes of chemicals (e.g., carcinogens, irritants, and CNS depressants). Then when consensus is reached on the formulae, the information on the various chemicals need only be put in to the "master equations," which would yield a comprehensive list of PELs for hundreds of chemicals.
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> The lack of transparency in OSHA's process for selecting the initial chemicals reinforced the perception that some special interest groups were more effective than others in preventing their chemicals from 'getting listed'. This issue needs to be hit 'head on' by the agency. There seems no better way than to share publicly the data and analyses that supported the Agency's proposal. OSHA should then encourage technical comments on this information. After having assembled up-to-date information that is "more or less" accepted by the stakeholders, the Agency should then publish several different algorithms for establishing a priority list.

In summary, the process of choosing chemicals must be as objective as possible, based on sound scientific principles and specific criteria. The stakeholders must be given an opportunity to participate in every phase of this process. A weight-of-evidence process for judging the overall body of toxicological and epidemiologic data must be developed which clearly states procedures for evaluation of individual study data.

3. For compliance purposes OSHA has defined PELs as values not to be exceeded. When designing exposure-monitoring programs to determine exceedances, employers must assign a statistical interpretation to the PEL. Therefore, OSHA should continue to provide guidance regarding suitable statistical interpretations. Employers can thus design effective performance-based exposure monitoring programs that are consistent with OSHA's expectations.

OSHA has provided some guidance regarding the statistical interpretation of various PELs. In the preamble to the 1987 benzene standard, OSHA acknowledged that exposures derive from continuous distributions where there is some finite probability of a random overexposure, even in a controlled work environment. OSHA stated, in both the benzene preamble and the preamble to the 1978 lead PEL that the long-term average exposure should be "well below" the PEL. The 1992 formaldehyde standard included a nonmandatory appendix that suggested that statistical tests could be used as part of an exposure sampling strategy:

> … a properly designed sampling strategy showing that all employees are exposed below the PELs, at least with a 95 percent certainty, is compelling evidence that the exposure limits are being achieved.

This appendix was derived from the NIOSH 1977 *Occupational Exposure Sampling Strategy Manual* (OESSM), in which NIOSH stated:

> In statistical terms, the employer should try to attain 95% confidence that no more than 5% of employee days are over the standard.

The exposure profile — or distribution of exposures — of a similar exposure group and by extension, the exposure profile of each member of the exposure group should be controlled to the point that the 95th percentile exposure is less than the PEL. Statistically analyzing the data and determining if the 95% upper confidence limit for the 95th percentile is less than the PEL can develop compelling evidence that the exposure profile is controlled.

If a substance is strictly a chronic disease agent, the EASC suggests that it is reasonable to focus attention on the long-term average exposure (LTA) or mean of the exposure profile, as our traditional time-weighted average (TWA) PELs have targeted. In the absence of specific guidance, it is reasonable to set a long-term average occupational exposure limit (LTA OEL) at one-third or less of the single-shift PEL. Several statistical tests are available for determining if the true mean is less than the LTA OEL.

In summary, the EASC recommends that, as a general principle, exposures be controlled so that the 95th percentile is less than the PEL for both short-term exposure limits and full-shift TWA exposure limits. If exposures are monitored and controlled according to the EASC guidance, this probability should be no more than 5%, and probably less.

Based on the guidance in the preambles to the benzene and lead PELs and Appendix B of the formaldehyde PEL, it could be argued that such an exposure-monitoring program would be considered appropriate for monitoring exposures to these substances. However, OSHA provides no similar guidance for assigning a statistical interpretation to the Z-table PELs or for the other single-substance 6(b) standards. Furthermore, the sampling strategy specified by OSHA in each of the 6(b) standards will not reliably detect poorly controlled work environments.

OSHA should clearly state both the immediate and long-range goals for chronic disease- agent PELs. For example, the long-range goal might be to reduce the long-term mean exposure, as averaged over, say, one or several years of exposure, to below one-half or one-third of the single-shift PEL. The immediate goal might be to limit the probability of exceeding the PEL to 5% or less. OSHA should clearly state the goal for controlling short-term exposures when there is a short-term exposure limit (STEL) or ceiling standard. For example, the target might be to limit within-shift exposure variation so that the probability of exceeding a short-term exposure limit or ceiling standard is no more than 5% or 1%, respectively.

Industrial hygienists could then design performance-based exposure monitoring and data analysis schemes that are both consistent with these goals — or statistical interpretations — and based on state-of-the-art practices. Data collected, analyzed, and interpreted under such an exposure monitoring program would constitute "compelling evidence," as mentioned in formaldehyde standard, for demonstrating to OSHA that exposures are routinely controlled.

4. OSHA should adopt a peer-reviewed guideline for the derivation of PELs. PELs must be based on the best scientific information available and must include a well-documented critical evaluation of the supporting information. Appropriate uncertainty factors also must be applied to compensate for the inherent uncertainties in the existing data and extrapolation to human populations.

Need for Peer-Reviewed Guideline

A peer-reviewed guideline for the derivation of PELs is needed to provide consistency. Such a guideline could also be used by the private sector to derive occupational exposure limits for agents that do not have legal or consensus standards. The guideline should address data collection and evaluation, identification of the critical endpoint, methodology or model selection in deriving the limit, and documentation requirements. Criteria for the selection of an 8-hour TWA, short-term exposure limit (STEL), and ceiling limit should be clearly established. Likewise, criteria for the designation of a skin notation should also be delineated.

Alternative Work Schedules

Since alternative work schedules have become more commonplace, they should be addressed in the PEL guidance. The body of knowledge concerning risk assessment and management will continue to grow as a result of strong research efforts in this area. Therefore, the methods used in establishing PELs must be part of a dynamic process, inclusive of innovative improvements as they are verified and peer reviewed. There is a particular need to incorporate means whereby inherent uncertainties in the risk assessment process can be addressed.

Use of Best Available Data

PELs should be based on the best available data concerning relevant toxicity and exposure potential. Information sources can include on-line databases, standard texts, and solicitation of potentially important unpublished data from sources such as manufacturers and users. Every effort should be made to obtain original references for all data, since review articles and other secondary references frequently contain errors or significant omissions of relevant information.

Furthermore, it is often difficult to evaluate the technical merits of data cited in secondary references. Unpublished, confidential company reports should not be used unless a publicly available summary can be provided that contains sufficient detail as to the methods used, results observed, and conclusions drawn, so as to permit a critical review of the adequacy of the report.

Data to be collected include physicochemical properties, toxicity, toxicokinetics, toxicodynamics, nuisance properties (e.g., odor), and exposure and population parameters. Available toxicity data vary widely in nature and quality from agent to agent. Therefore, all available data should be reviewed and their quality and value as a basis for setting a PEL determined. Several aspects of study design and reporting must be considered when assessing the quality of toxicity data; guidance is available from many sources.

The toxicity data documented for each PEL should include a summary of pertinent human and animal data, genotoxicity data, summaries of cancer hazard and reproductive hazard evaluations, where available, and a summary of pertinent metabolism/toxicokinetic data. Some chemicals may cause effects in animals at inordinately high doses, under unusual exposure conditions, or under other unique circumstances. The relevance of such information should be considered. If available data on human experience establish results different from those obtained in animals, the human data should take precedence. Human experience should be emphasized to the extent credible data are available.

The goal of the toxicity data review is the delineation of all adverse effects relevant to the setting of a PEL. The rationale for a PEL may be derived from epidemiology data or human experience. When human data are lacking, the PEL will be derived from animal data. The basis for the PEL should generally be the adverse effect and associated NOAEL/LOAEL (no observed adverse effect level/lowest observed adverse effect level) occurring first on the dose-response curve. This is referred to as the critical effect.

The NOAEL is defined as the exposure level at which there is no statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control. Effects may be produced at this level, but they are not considered to be adverse. The LOAEL is the lowest exposure level in a study or group of studies that produces statistically or biologically significant increases in frequency or severity of adverse effects between the exposed population and its appropriate control. The manner by which other adverse effects are prevented by protecting against the effect chosen as the rationale for the PEL should be indicated in the documentation.

A risk assessment methodology to characterize the dose-response curve and derive the PEL should be selected based on the nature of the effect and quality of data. Several quantitative risk assessment methods exist that can be applied to low dose risk estimation of carcinogenicity; these include linear, mechanistic, tolerance distribution, time-to-tumor, and biologically motivated models. An uncertainty factor approach would be appropriate for nongenotoxic effects where exposure thresholds can be demonstrated.

Limitations of the traditional uncertainty factor method in PEL setting include lack of risk comparisons, limited consideration of the slope of the dose-response curve, and use of NOAELs that are dependent on test sample size and therefore, may not be highly certain. In order to address some of these limitations, different models could be considered to develop the dose-response curve. For example, the benchmark dose approach, which is a statistical confidence limit on a dose corresponding to a specific increase in the response rate over the background rate, may address these shortcomings in some instances. This method utilizes the entire dose-response curve, does not require that a NOAEL be identified, and allows estimation of risk at multiple exposure levels.

Comparative toxicokinetic data should be utilized when available to help address uncertainty related to interspecies extrapolation. Generally, if credible human data exist, minimal uncertainty factors should be applied as compared to situations where only animal data are available. The seriousness and reversibility of the critical effect should also be considered in developing an appropriate uncertainty factor. For example, a lower factor may be used where the PEL is based on avoidance of localized, reversible, sensory irritation, whereas higher factors should be applied where the critical effect is systemic in nature.

Default assumptions should be used only in the absence of adequate data and should be scientifically defensible. Supporting documentation for the risk assessment and PEL derivation should include a discussion of uncertainties identified and the means by which they are addressed. Identified uncertainties should drive future research projects.

Summaries of Studies

Summaries of those studies determined to be adequate and appropriate for use in setting PELs should be included in the PEL documentation. Those data deemed valuable from studies judged inadequate will also be included with appropriate discussion of study inadequacies and data limitations; these data may be considered supporting in nature but should not be the basis of the PEL.

5. Employers have a responsibility to assess the risks to the health of their workers and adequately control worker exposures to hazardous substances or agents for which there are no PELs. Employees must be fully consulted in the development of these risk assessments and informed of the results. Tools such as occupational hazard banding, a hierarchy of OELs approach, and risk-based quantitative analyses should be employed where appropriate when PELs are not available.

Even a streamlined and simplified PEL rulemaking process will be a relatively slow process that will never be able to generate exposure limits for all of the substances that are likely to present a health risk to employees. The biggest issue for all OEL-setting bodies is the lack of minimal toxicological data on most chemicals or mixtures, adequate resources to interpret existing data sets, and the ongoing need to protect workers during the consistent introduction of new chemicals being launched into the marketplace. In the absence of these limits, employers still have a responsibility to control exposure to protect against material impairment to health or diminished functional capacity.

To ensure workers are adequately protected, employers should formally document an assessment of risks created by any work and the means for controlling these risks. This documentation involves evaluating the hazards of the substances or agents (their anticipated health effects); likely target organs, and the synergistic effects that may occur from combined or sequential exposures to other substances); the likely routes of exposure (inhalation, dermal, ingestion, or subcutaneous); the nature of the extent to which work groups could be exposed (the duration, frequency, and intensity of exposure); and the effectiveness of controls.

These risk assessments must be developed in consultation with and the involvement of affected employees. They should be reviewed regularly and also whenever there is a significant management change in operations, health information, or processes in general.

In some instances there may be sufficient information available from manufacturers, suppliers, the occupational medicine literature, and industrial toxicology or other disciplines to set a self-imposed provisional working standard. In these situations, employers should develop recommended exposure limits using the best scientific information available exposure monitoring data to confirm compliance with these limits. These provisional exposure limits and information about effective controls should be provided to users of these substances, whether employees or customers.

Responsible product stewardship and corporate social responsibility suggest that employers should observe OELs for the non-PEL substances present in their workplaces that may present a risk to their employees as a result of exposure. These limits could be based on RELs, TLVs®, or WEELs, or on the recommendations of the supplier or manufacturer of the substance. OSHA's recommends that employers consider using the alternative OELs values found in OSHA's Annotated PEL Tables online.

Ideally, OELs should be risk-based exposure values derived from human experience or toxicological studies. Where such data are not available, structure activity relationships (SARs) may be used as a last resort. Such risk-based exposure limits, together with explicit operational precautionary and control statements, be included as part of an enhanced hazard communication program that has as its core an operational safety data sheet (SDS). Operational SDSs provide the prescribed procedures, the results to be recorded, and the criteria for defining adjectives such as "use a suitable respirator" or "employ good local ventilation."

In practice, however, the burden of these requirements would fall on the producers of non-PEL substances (generally larger companies), since they would be the first employer to have such substances in their workplace and are presently required to furnish an SDS to their customers. Adoption of these recommendations would be economically efficient: it would internalize the cost of providing the health protection data needed by the multiple users of non-PEL substances on the relatively few suppliers or importers of substances.

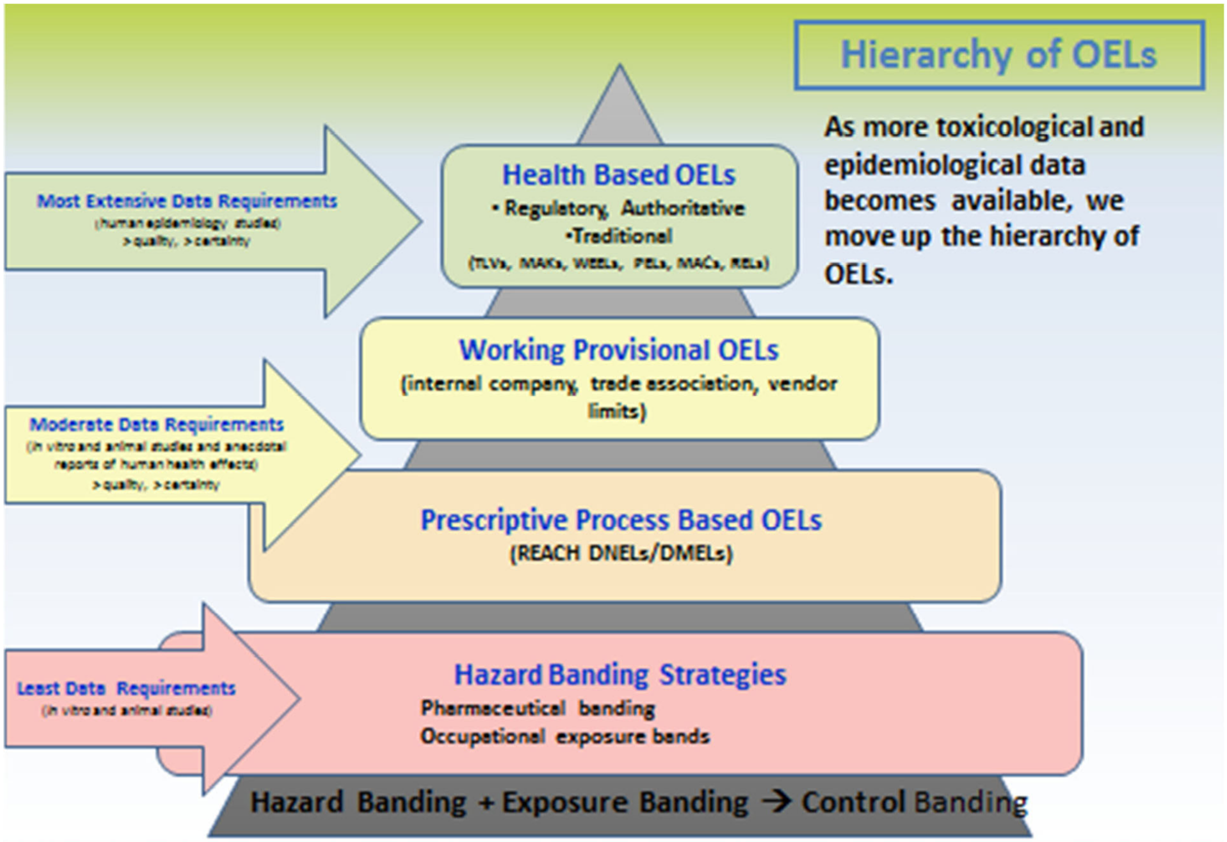
For some substances, medical examinations would be a critical element of worker protection. Employers need to establish programs to perform appropriate medical tests when needed. The principles obligating employers to perform workplace risk assessments have been the framework of worker health legislation in many countries, particularly within the European Union. These requirements would logically be a part of any comprehensive health and safety program standard issued by OSHA. This approach should be adopted to supplement programs for updating permissible exposure limits.

Many industrial hygienists (IHs) perform exposure risk assessments and risk management using alternative strategies such as occupational exposure banding (OEB) when PELs or other OELs do not exist. This process has been successfully used for over 20 years in the pharmaceutical industry, where OELs rarely exist.

OEBs can be developed with minimal data, highlight areas where data are missing, support the definition of OEL-ranges for families of materials, support chemical hazard identification by structural activity relationships and functionality, and provide a screening tool for the development of OELs. NIOSH's initiative for a unified approach of developing OEBs using the hazard banding techniques will standardize the way hazards are evaluated. It also provides a road map for organizations, OSHA included, to recommend a hazard category and subsequent risk control strategies.

Risk-based exposure limits apply mathematical modeling to existing toxicology data to estimate a true predicted level of risk. The information derived would better inform all stakeholders of the underpinning, meaning, and certainty of our limits.

And finally, a growing segment of our profession has embraced, both here and abroad, a "hierarchy of OELs" approach to selecting limits (see figure), which incorporates occupational hazard banding, prescriptive OELs (such as new chemical exposure limits (NCELs), or derived no effect levels – DNELs), provisional (i.e., company) OELs, and traditional OELs (PELs, TLVs®, WEELs, RELs, and so on) when they exist.



6. PELs should be consistent across occupational populations and should be accepted by other federal agencies when the goal is protecting occupational health.

PELs are derived for use by occupational health professionals to protect the health of workers in their environments. To accomplish this, certain assumptions are made. The population at risk is assumed to be healthy and ranging in age from 16 to 72 years. Exposures are usually periodic, averaging 40 hours or more per week. There may be susceptible or hypersensitive individuals for which the PEL will not prevent adverse effects. Thus, the population that the PELs are intended for still may exhibit illness or injury, particularly when technical and economic feasibility concerns modify a health endpoint to a higher PEL.

Environmental Versus Occupational Limits

PELs, TLVs®, and WEELs at times have been inappropriately applied in public health situations and not applied in the occupational sector alone (e.g., control of air pollution exposures for the general public). Significant differences in general population exposure conditions and protection goals eliminate the value in applying occupational limits to the control of environmental exposures for the general public.

Most often, the goal of public health is the elimination of risk to a population of varied ages and varying degrees of health and susceptibility to adverse insults. In the occupational environment, susceptible individuals can be protected via a hierarchy of controls. This hierarchy of controls is generally not available within a community. It is neither appropriate nor scientifically sound to use occupational limits in non-occupational applications and vice versa.

Consistency in Application Regardless of Jurisdiction or Control Feasibility

PELs must be consistent across occupational populations including, for example, manufacturing operations and office environments. PELs are health-based levels, which must take into account the common finding that a single chemical can have varying adverse effects at different exposures or doses. For example, a chemical may be a potential systemic chronic health hazard at one dose level and also be a transient sensory irritant at a different exposure or dose level.

The development of a single PEL must take into account all known adverse effects associated with that chemical. PELs must be set to protect against the lowest documented effect level based on sound science, thereby affording protection against effects occurring at higher dose levels. Multiple "tiered" PELs intended to be applied in different occupational settings are not recommended when practicing good industrial hygiene. To ensure consistency across the occupational workforce, PELs must be derived to protect against adverse effects across either single or both gender populations.

Health-based PELs should be set without regard to control feasibility in an industry or workplace, but not set where PELs cannot be measured or analyzed. It is true that workplace exposures may vary between industries, but it is also true that an agent's adverse health effects remain constant.

Since the ultimate goal of a PEL is to control adverse effects, it is inconsistent to derive limits for varying industries based on control technology. In instances where engineering control is not feasible, enforcement directives should allow compliance via additional alternate control strategies (e.g., administrative controls or respirators as a last choice). Because these control strategies, especially the use of respirators, are often less effective than engineering controls, they should be used under the guidance of occupational health professionals.

Federal Agency Agreement to Accept Common PELs

To further ensure consistency, when the goal is protecting occupational health, OSHA PELs should be accepted by other federal agencies. Protecting public health in federal agencies is different from in an occupational environment. OSHA's primary goal is occupational safety and health. As such, the agency is in the best position to understand, evaluate, and promulgate appropriate occupational exposure standards.

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General Comments from AIHA Volunteer Groups

In addition to providing the AIHA white paper/position statement on the issue of permissible exposure limits, AIHA requested its volunteer groups to submit comments in response to the OSHA Request for Information (RFI). The following comments should not be considered official comments from AIHA, but rather, general comments submitted by members of three AIHA volunteer groups.

Volunteer Group 1 – AIHA Exposure Control Banding Committee (ECBC)

Question IV.C.1: Should OSHA consider greater use of process oriented regulations, such as regulations on abrasive blasting, welding or degreasing as an approach to health standards? Should an approach be combined with a control banding approach?

Response

Many employers use similar unit operations or tasks to manufacture a product or provide a service. In many cases, the hazards and exposures associated with these tasks have been evaluated, and control approaches have been developed and validated. Rather than promulgate new health standards for thousands of unregulated chemicals, OSHA either could issue voluntary task-based control guidelines or it could require employers to comply with process oriented regulations that are similar to the standards OSHA has already developed for abrasive blasting, welding, degreasing, and, most recently, lead and silica in construction.

When it developed the lead and silica in construction standards, OSHA recognized that the collection of initial exposure monitoring data at an ever-changing construction site would be difficult. Therefore, the lead (1926.62) and silica (notice of proposed rulemaking) standards require employers to protect employees with defined control strategies for selected tasks during the assessment of exposure (lead) or in lieu of initial monitoring (silica).

Essentially, OSHA assigned control bands to selected construction tasks. The bands were based on anticipated exposures and the effectiveness of validated controls. Appropriately, employers were provided resources such as "Controlling Silica Exposures in Construction" (OSHA 3362-05) to assist them with implementing these controls.

Process oriented regulations are especially attractive in settings where quantitative data is difficult to collect. Examples include machining with metalworking fluids, working with nanosize particles, spraying two-part polyurethane foam, welding, soldering with a flux that releases complex thermal decomposition products, and remediating mold in a workplace. Employers frequently overlook the chronic health effects associated with these and other processes because chronic health effects are not immediately recognized.

Process oriented regulations ensure that chronic health hazards are addressed in risk assessments. The American National Standards Institute (ANSI), NIOSH, OSHA, and various governmental, professional, and trade organizations have developed best practice guidance resources for these and other settings. Implementation of the guidance ensures that workers are protected.

Risk assessments in industry target high-profile health hazards and often ignore the common wisdom to pick the "low-hanging fruit." Some low and medium risks can be controlled very easily, yet these are not considered by systemic design; this can be addressed with control banding (CB).

The United Kingdom's Health and Safety Executive (HSE), an independent regulatory agency, demonstrated the benefits of control banding through its COSHH initiatives for small and medium-sized employers. (COSHH stands for Control of Substances Hazardous to Health.) In addition to its generic control guidance sheets, the e-tool COSHH Essentials has developed multiple industry-specific direct advice sheets.

The best practice guidance documents address multiple production and service industries. The recommended controls provide general design guidance so that employers can construct effective controls. The task-based guidance documents identify a best practice for controlling the hazard, provide illustrated details on effective operation and maintenance techniques, and offer additional checklists for supervisors and workers.

Additional process oriented best practice guidance could be developed with input from manufacturers. For example, in Europe, manufacturers of high-use chemicals are expected to provide Tier 1 and Tier 2 guidance (exposure assessment and risk characterization of tasks). Since the HSE introduced COSHH Essentials, multiple enhanced control banding models have been introduced. These next-generation CB models and resources, such as the Advanced REACH Tool, will be used by manufacturers to develop exposure scenarios. These scenarios describe the operating conditions and risk management measures that have been identified by the supplier. As a result, end-users will have better information on the hazards of chemicals and guidance on how to use them safely.

As part of an employer's injury and illness prevention programs, OSHA could require employers to conduct a job hazard analysis, which could include reviewing (and possibly implementing) the available best practice guidance for specific processes. OSHA or NIOSH could continuously publish these best practices as suggestions or examples for employers to utilize. Employers would be encouraged and expected to implement the best practice guidance unless they can demonstrate that the exposure potential variables in their setting reduce risk (e.g., limited frequency, small quantities). Enforcement in these situations could identify whether best practice controls are in place, maintained, and appear to work. If there is deviation from best practice controls, task and exposure assessment reports should be developed by competent persons to identify conditions and parameters of control.

Question V.A.4: Are there other acceptable methods that can be used to develop hazard information for multiple chemicals within a group?

Response

The control banding approach builds on currently acceptable methods for development of hazard information and control. The hazard band approach utilizes traditional toxicology information such as chronic toxicity, acute toxicity, carcinogenicity, irritation, and sensitization. The control banding technique supports traditional IH methods for control including containment, ventilation, work practices, and personal protective equipment. The traditional tools of elimination, substitution, and modification are also supported within the banding methodology.

Other methods that utilize these principles include the Canadian Centre for Occupational Health and Safety's "Fact Sheet on Control Banding Approach," the 2007 *GTZ Chemical Management Guide for Small and Medium Sized Enterprises* (German Technical Cooperation Agency), COSHH Essentials, and tools provided by the International Labour Organization (ILO).

Question V.B.8: How could OSHA use the information generated under HazCom 2012 to pursue means of managing and controlling chemical exposures in an approach other than substance-by-substance regulation?

Response

As OSHA notes on its "Transitioning to Safer Chemicals" website, informed substitution and alternatives assessment are key elements of an effective chemical management system that best protects workers. Employers should be able to readily identify high-hazard chemicals with information generated under the Hazard Communication (HazCom) 2012 standard.

Employers will recognize that products with the signal word "Danger" are more hazardous than products with the signal word "Warning." In addition, they will appreciate that within each hazard class, chemicals with a category 1 designation are more hazardous that chemicals with category 2, 3, or 4 designations. Employers and employees can use the information from SDSs to make informed substitution decisions and identify which potential chemical exposures are of greatest concern. NIOSH's Occupational Exposure Banding project should help employers use data from SDSs to categorize chemicals into hazard bands.

Question V.B.9: How could such an approach satisfy legal requirements to reduce significant risk of material impairment and for technological and economic feasibility?

Response

The HazCom 2012 standard with Globally Harmonized System (GHS) criteria for the classification and labeling of chemicals greatly enhances the original hazard communication standard. The AIHA Exposure Control Banding Committee (ECBC) recommends that the standard for hazard characterization as a starting point for health hazard banding and occupational exposure banding of chemicals.

In light of several regulatory actions and demonstrated inability for an industry to handle chemicals and health hazards an industry association decided to develop a control banding system similar to the ILO Chemical Control Toolkit. The industry has some very sophisticated chemistry; however, the health aspects of chemicals are often overlooked, and the ability to associate a health hazard from an SDS to a health hazard category may be difficult for field-level workers.

Control banding is a risk assessment technique with smarter science-based inputs and thoughtful, well-conceived outputs. Risk assessments in other cases are only as good as the people around providing input into the assessment. Qualified occupational safety and health professionals are the most qualified to address especially hazardous environments and conditions.

Question V.B.10: Please describe your experience in using health hazard and/or control banding to address exposures to chemicals in the workplace.

Response

The ECBC acknowledges that chemicals are introduced at a rate that exceeds OEL development. The recently proposed NIOSH Occupational Exposure Banding process will be useful to develop risk guidance for those chemicals. As noted in OSHA Exhibit 127 and the RFI (page 61415), the proposed OEB process classifies chemicals into one of five bands and "includes a three-tiered evaluation system based on the availability of toxicological data to define a range of concentrations for controlling chemical exposures."

Members of the AIHA ECBC have had a variety of experiences using health hazard banding and control banding to address exposures to chemicals in the workplace, such as chemical manufacturing, general manufacturing, oil and gas, research and development, academia, healthcare, defense, biosafety, and services. All have had positive experiences classifying hazards, observing others classifying hazards, and having workers with various levels of education understand the resultant controls.

One AIHA ECBC member presented a series of CB workshops for joint labor-management teams from a variety of workplaces. The participants learned how to use one CB model, the United Kingdom (UK) Health and Safety Executive's Control of Substances Hazardous to Health (COSHH) Essentials Toolkit. After the initial training program, the investigators used follow-up workshops, questionnaires, and site visit data to evaluate the training curriculum and assess the utility and effectiveness of this CB model.

Although they thought that there was considerable room for improvement, the participants appreciated the fact that the model promoted a discussion of risk between workers and managers. The participants successfully used the model to identify high-hazard chemicals, and they observed that industry-specific "direct advice" guidance was valuable, especially when COSHH Essentials' generic chemical by chemical CB approach proved difficult (Bracker, *JOEH*, May 2009). This ECBC member continues to teach small employers about the value of hazard banding strategies and industry-specific direct advice resources in her capacity as a health consultant for small employers through OSHA's 21D program.

Health hazard banding and control banding are comprehensively being applied at Lawrence Livermore National Laboratory (LLNL), and its successes are being shared and implemented nationally and internationally. This occupational and environmental risk management (OERM) is based entirely on banding strategies, reflecting the need for clear and consistent communication of risk within the environmental health and safety (EHS) professions, and it was considered essential for achieving prevention of work-related risks.

Utilizing fundamental IH principles, a risk level-based management system (RLBMS) was developed to deliver the most elusive toll necessary for success; risk communication within and between our EHS professions. With a singular EHS risk communication construct, a comprehensive OERM program has been built. The RLBMS is based on the success of control banding applications internationally that are reflected in the expansive reference list submitted as a response to V.2 of this RFI.

Bringing together the basic banding strategies, the RLBMS has now been expanded well beyond potential workplace chemical exposures and has been expanded to cover all IH regulatory requirements for chemical, physical, and biological agents within a risk assessment and control (RAC) database. As an outcome, the utility of using health hazard banding as part of the initial qualitative risk assessment process has proved beneficial, not only in standardizing controls, but also in prioritizing where and when quantitative monitoring needs to be performed.

Therefore, health hazard and control banding has proved itself as an essential commodity for a comprehensive IH program. In addition, the simplification of risk communication through banding strategies also provides an essential de-confliction of multidisciplinary controls for an individual task. This banding process provides workers with simple, clear, and concise guidance on how to reduce risk, achieve exposure prevention, and obtain worker-based feedback and improvement on a daily basis. Its success has also built collaboration between both Los Alamos National Laboratory and LLNL to create a common risk assessment process within the RLBMS.

A comprehensive work planning and control (WP&C) system is being implemented based on a singular, multidisciplinary RAC database that expands the banding strategies for the industrial safety, health physics, environmental analyst, explosives safety, ergonomics, and fire protection professions. The WP&C and RAC database are established as compliant with Occupational Health and Safety Assessment Series (OHSAS) 18001, ISO 14001, and ISO 9001.

With RLBMS and this comprehensive example of applying banding strategies to reduce worker and environmental exposures, the ability to combine an occupational safety and health management system (OHSMS) with an environmental management system (EMS) brings the opportunity for a new OERM process — but also a new vision of how OSHA and EPA can work together on a singular EHS regulation.

Hazard Assessment and Health Hazard Banding

After the hazards are derived and identified from the prescribed tasks in a concise scope of work, each of the EHS disciplines performs a documented hazard assessment using health hazard banding for each of their hazards in the RAC database. This procedure utilizes the RLBMS that divides each hazard into four categories that are presented, lowest to highest, as Risk Level 1 (RL1) to RL4. EHS professionals can use both example tasks at each RL or assessments for a given hazard that was previously completed by their fellow disciplines.

Risk Assessment

Once the RL is derived to determine the relative severity of a given hazard, the components of exposure probability are then obtained from the work scope and documented to complete a qualitative risk assessment.

Control Banding

Each hazard's RLs are paired with commensurate controls following the traditional IH hierarchy in source documents that are developed by the subject matter expert. Using IH as an example, there are 35 separate hazard source documents that include OSHA-related materials. All this information is automatically filled in within the RAC database and then modified to the work scope at hand by the discipline. This provides an indirect hazard-to-control banding approach.

Classic control banding tools are also used within this process, including the BAuA (German Federal Institute for Occupational Safety and Health) EMKG toolkit for chemicals without TLVs® or PELs and the quantitatively validated CB Nanotool. In addition, there are RL derivation tools for oxygen deficiency, toxic gas, and welding. All RL3 and RL4 hazard outcomes have required follow-up actions, including classic chemical exposure assessment monitoring, and RL2 has periodic validation protocol.

Question V.B.12: How can OSHA most effectively use the concepts of health hazard and control banding in developing health standards?

Response

The NIOSH OEB framework and tool under development are being subjected to multiple rounds of internal and external validity testing. The completion of this validated framework and tool could assist OSHA in assessing chemical hazards, prioritizing them, and determining a priority order for potential regulation or guidance. OSHA could also consider a novel approach of recommending OEBs in conjunction with a comprehensive safety management system. This approach could complement the current health-based standard approach.

Question V.B.11.: Are additional studies available that have examined the effectiveness of health hazard and control banding strategies in protecting workers?

Response: There are several articles that describe studies conducted to examine the effectiveness of health hazard and control banding strategies in protecting workers. Examples are listed below. (See next section for details on the International Control Banding Workshops, abbreviated here as ICBW.)

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Further International CB Workshop information and research can be obtained from the following websites:

- ICBW1. First International Control Banding Workshop. London, England, November 4-5, 2002. http://www.bohs.org/mod.php?mod=fileman&op=view_cat&id=14.
- ICBW2. Second International Control Banding Workshop. Cincinnati, Ohio, March 1-2, 2004. http://www.acgih.org/events/course/controlbandwkshp.htm.
- ICBW3. Third International Control Banding Workshop. Pilanesburg, South Africa, September 21, 2005. http://www.saioh.org/ioha2005/Proceedings/SSI.htm.
- ICBW4. Fourth International Control Banding Workshop. Seoul, South Korea, July 1, 2008. http://www.ioha.net.
- ICBW5. Fifth International Control Banding Workshop. Cape Town, South Africa, March 25, 2009. http://www.ioha.net.
- ICBW6. Sixth International Control Banding Workshop. Rome, Italy, September 27, 2010. http://www.ioha.net.
- ICBW7. Seventh International Control Banding Workshop. London, England (Sessions 8c, 9c, 11c, 12c), http://www.ioha2015.org/ioha-2015-presentations.

Volunteer Group 2

OSHA will never have enough resources and time to develop PELs for all toxic chemicals. Thus, the agency has to make strategic decisions about which ones justify the effort. For a small number of chemicals where there is evidence the PEL is too high, a considerable number of workers are exposed to these high levels, and there is credible evidence, these PELs should be prioritized and regulated as individual substances (similar to silica). Existing standards like the CAL-OSHA PELs, NIOSH RELs, and ACGIH TLVs® and prioritizations should be used whenever possible to guide this effort.

Some chemicals for which PEL updates might be a priority would include:

- 1-bromopropane
- carbon monoxide
- diesel exhaust
- glutaraldehyde
- manganese
- mercury
- n-hexane
- perchloroethylene
- styrene
- toluene

Other priorities where chemicals could be grouped and regulated as a class include:

- isocyanates
- welding fumes
- chemotherapeutic agents
- halogenated anesthetic agents with nitrous oxide
- metalworking fluids
- dust (not otherwise characterized)

These chemicals and groups can be tackled a few at a time each year over a decade or two. (This in itself may require a dramatic increase in OSHA's standard setting budget, which is currently only about 3% of its overall budget.) OSHA should encourage substitution of safer less toxic alternatives whenever possible.

Beyond high-priority chemicals and groups, OSHA needs to require a risk assessment process whereby companies, using the information obtained from the chemical safety data sheets (SDS) in conjunction with knowledge of how the chemicals will be used (exposure conditions), can perform a simple risk assessment and develop control strategies.

The new ANSI A10.49 standard, *Control of Chemical Hazards in Construction*, follows this approach and has seen significant support from industry. This approach is similar to control banding, which has been used successfully in several industries in the United States and more comprehensively in Europe.

Task-based regulation is also a very useful approach and OSHA has had some success with this approach in the asbestos and lead standards. OSHA is pursuing this approach as well in its proposed silica rule. The goal is to identify high-exposure tasks and effective controls for those tasks. Mandating those controls whenever the tasks are done effectively reduces overall exposures significantly. Such requirements make compliance much easier for employers, don't require as much air sampling, and are easier for compliance officers to enforce.

As thousands of new chemicals enter commerce each year, OSHA simply cannot keep up. The burden to protect worker health must be placed on employers and chemical manufacturers to do risk assessments and plan accordingly. An essential element in this process must be active worker involvement in the risk assessment as well as the development, implementation, and monitoring of control plans. Workers must have the authority to question and challenge the assessments and control plans.

Volunteer Group 3

General Comment

We applaud this challenging and much-needed effort by OSHA. As occupational epidemiologists, we often assign exposures to workers or worker groups after they occur, using available information from company records, or more often, in the absence of that, from other sources, the literature, or professional judgment. We see any new regulation as an opportunity to require appropriate recordkeeping regarding worker exposure information, including information characterizing the workplace, workforce, work practice, and exposure groups.

Recommendation

Recordkeeping will be particularly important if qualitative or semi-quantitative methods are adopted such as hazard banding or control banding. We urge this topic be added to the list of considerations for whatever regulation is developed. (Reference *AIHA Exposure Assessment Strategies*, Chapter 9, 4th edition).

General Comment

While epidemiology is mentioned several times in the report, it is not included in the specific analyses that could be used now or in the future to determine appropriate PELs.

Recommendation

Epidemiological studies should be described within the context of model generation/validation, as a weight-of-evidence input parameter, and encouraged where employee populations at risk exposure are large and/or the potential health effects are in question.

General Comment

This statement indicates the importance of epidemiological studies:

> The Agency generally prefers high quality epidemiologic studies for dose-response analysis over experimental animal models, provided there is adequate exposure information and confounding factors are appropriately controlled (page 61392, paragraph 2, line 15).

However, it suggests that if the studies are not of “high quality,” they should not be used to evaluate potential health effects of chemicals.

Recommendation

Include in this section, or elsewhere, that epidemiological studies should be used in a weight-of-evidence and/or directly to support development of PELs. Further, there should be a discussion of what would be considered a “high-quality epidemiology study” and whether there is a consensus on types and number of epidemiology studies required to establish a causal relationship between an exposure and outcome.