1 Introduction

The AIHA Guideline Foundation (AGF) researches and educates the public about exposure levels for chemical and physical agents and stressors. The AGF also develops exposure guide values, and related guideline documents, for chemical and physical agents and stressors. These guide values and supporting documentation related to worker and community exposure levels for chemical and physical agents and stressors are published by the AGF.

Workplace Environmental Exposure Levels (WEELs), Biological Environmental Exposure Levels (BEELs) and Emergency Response Planning Guidelines (ERPGs) are health-based guide values for exposures to chemical and physical agents.

WEELs are air concentration guide values for agents in a healthy worker's breathing zone. BEELs are concentration guide values for agents in biological media (e.g., blood, urine) of healthy workers. BEELs reflect internal dose. WEELs and BEELs are used to assess the potential for adverse health effects to healthy workers following exposures to agents that may occur day after day for a working lifetime.

ERPGs are air concentration guide values for single exposures to agents and are intended for use as tools to assess the adequacy of incident prevention and emergency response plans, including transportation emergency planning, community emergency response plans, and incident prevention and mitigation.

2 Purpose

To define and align the processes for developing new and revising existing WEELs, including health hazard bands; BEELs; and ERPGs, and to:

- Outline the basis for selection of candidate agents
- Align methodologies to obtain and analyze relevant data
- Provide for review of draft guide values by scientific peers
- Define a transparent process for approval and communication of proposed guide values
- Share human and informational resources effectively among the three volunteer groups
- Facilitate an efficient, cost effective process

The guide value development process is designed to take advantage of the expanding database resulting from voluntary testing programs. WEELs, health hazard bands, BEELs and ERPGs can only be established for agents with adequate data sets.

3 Scope

The guide value development process focuses on producing information for workplace and community health professionals that is related to an agent's health risk to workers or exposed people. This information may take the form of a health hazard band, a specific guide value, an exposure assessment supporting document that justifies a guide value, or a more-broadly based technical support document about the chemical, physical, and toxicological properties, exposure assessment, regulations, and risk assessment for the agent. The process includes a search and review of literature to obtain up-to-date scientific information, subject matter experts to interpretation of the data in the literature, and production of the necessary peer-reviewed guide values and documents.

4 Volunteer Group Membership

The AIHA Guideline Foundation (AIHA GF) Volunteer Groups are comprised of volunteer members of AIHA who are professionals with specific expertise relevant to guide value development. Any person interested in serving on one or more of the Volunteer Groups is encouraged to submit an application to the AIHA Guideline Foundation staff. Additional information regarding membership requirements and application process can be found at www.aiha.org/???.

At least annually, AIHA GF Volunteer Group Chairs review and analyze the group's membership roster to confirm the continuing eligibility of current full members and to help ensure that the members can provide a balance of desired scientific expertise and perspectives from diverse organizational affiliations.

AIHA GF Volunteer Group needs are communicated to staff by the Chairs. Staff coordinates the call for members, collects and collates the responses, and provides the applicants' information to the appropriate Volunteer Group Chair for review and approval by the VG members, in accordance with the current AGF administrative operating procedures (AOPs).

5 Roles and Responsibilities

Each Volunteer Group member is expected to author and review documents and guide values, participate in Volunteer Group meetings, and contribute to Volunteer Group discussions.

5.1 Author

- Conduct, or have conducted by staff, literature searches, as needed
- Determine if search results are acceptable
- Ensure unpublished data is requested from agencies, labor, and industry stakeholders through AIHA staff
- Identify, obtain, and review needed references
- Compile and review the data to determine the appropriate value(s)

- Draft Guide Rationale and/or Technical Support document
- Ensure copies of all cited references accompany the draft Guide Rationale and/or Technical Support document submitted to staff
- Revise the draft document to address review comments from Volunteer Group members and stakeholders

5.2 Reviewer

- Direct and facilitate initial review of the draft Guide Rationale and the Technical Support document
- Critically review the draft Guide Rationale and the Technical Support document and suggest revisions, as appropriate, to the author
- Ensure that the draft Guide Rationale and the Technical Support document is technically accurate and balanced

The reviewer and author are to work together to resolve the questions and recommendations raised by the Volunteer Group members and stakeholders during their review. More than one reviewer may be assigned.

5.3 Volunteer Group Chair

- Organize and preside over volunteer group meetings
- Identify first and/or second reviewers of the draft Guide Rationale and the Technical Support Document
- Coordinate the participation of external organizations in the review process with AIHA staff
- Prepare the budget, business plan and annual report for the Volunteer Group
- Appoint the QA/QC and Publication Coordinators and members of the cross-functional review team
- Assign agents to authors
- Serve as an ex-officio member of all subcommittees, task forces, and teams

5.4 Volunteer Group Members

- Review, revise, and approve Guide Rationales and Technical Support Documents through a formal balloting process
- Provide input to the Chair regarding assignment of agents to authors

Volunteer Group members represent a diverse body of health science professionals, including but not limited to emergency planners, epidemiologists, industrial hygienists, computer modeling

specialists, occupational physicians and toxicologists. Volunteer group members serve as independent scientific experts providing their best scientific opinions with the goal of ensuring the development of health-based guide values. During any Volunteer Group activity, members explicitly do not represent their employers, any specific organization, or any other legal entity.

5.5 QA/QC Coordinator

- Determine completeness of Guide Rationales and Technical Support Documents after balloting and receipt of external comments
- Ensure accurate incorporation of revisions and conformance to document format

5.6 Publication Coordinator

- Review completeness of the guide value reference set
- Ensure references are posted to the online guide value reference library

5.7 Cross Functional Review Team

- Manage the movement of priority agents through the hoppering process, using the initial filtering process to identify Bin 1 *Agents of Interest*
- Determine eligibility for promotion of Bin 1 agents to Bin 2, using the second filtering process
- Prioritize Bin 2 agents, request literature searches for agents of highest concern, and request review of pertinent literature by appropriate Volunteer Group members
- Review data and Volunteer Group recommendations, and together with the Volunteer Group Chairs, to determine adequacy of an agent's data set for establishment of a guide value and promotion to Bin 3
- Determine the need for updates to existing guide values

The cross-functional review team is comprised of representatives from each of the guide value volunteer groups who are appointed by the corresponding Volunteer Group chairs.

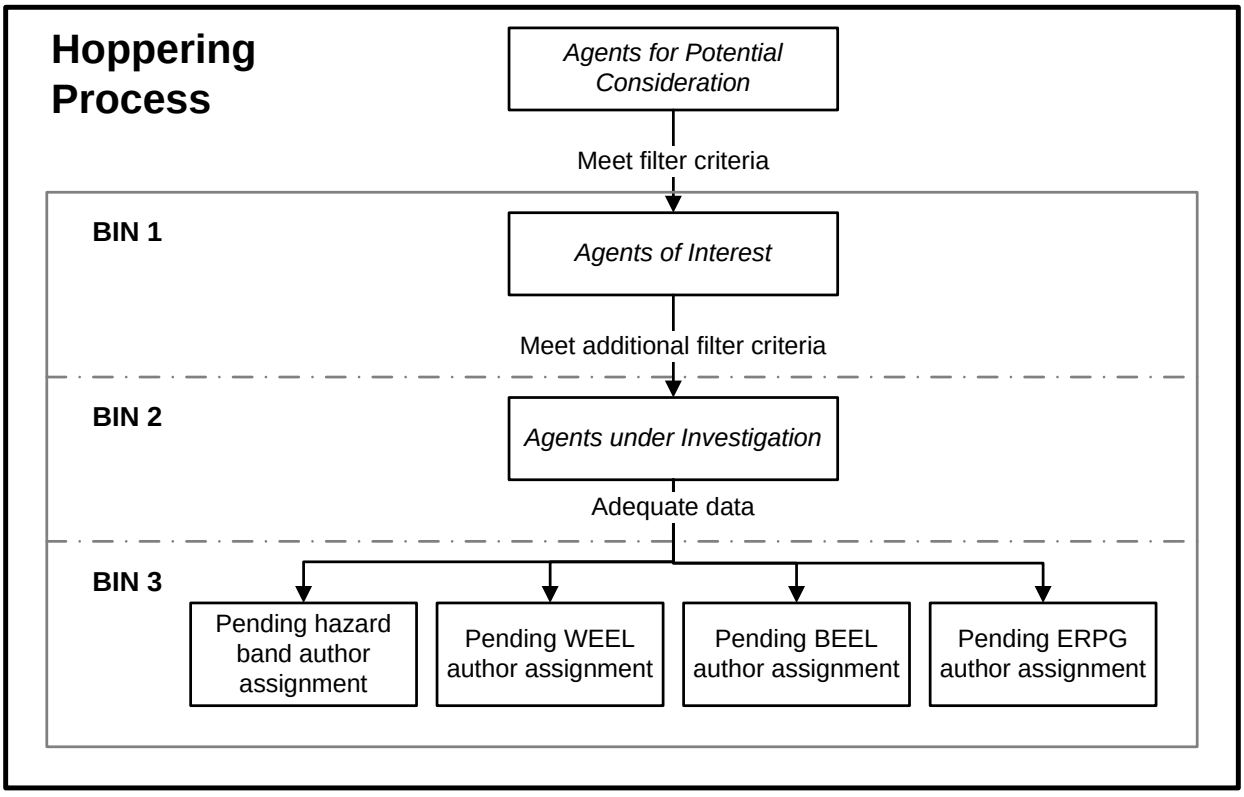
6 Selecting Candidates for Guide Values: Candidate Hoppering Process for New WEELs, BEELs, and ERPGs

An updated list of agents for guide value assessment is developed and maintained through the hoppering process. This process includes three bins to narrow the number of possible candidates to the priority candidates that have adequate data to support guide value establishment. The Cross Functional Review Team manages the movement of priority agents through the Bin process. The list of substances considered for a guide value development and their position in the hoppering process are to be published at least annually. This list will be available to stakeholders in the public domain.

The list of potential agents for inclusion in this hoppering process is compiled from:

- Lists of high production volume chemicals or agents
- Other priority chemicals or agents identified by:
    - Non-government agencies
    - Government agencies, including military and international groups (e.g., European Union, Health Canada)
    - Manufacturers and distributors
    - Transportation entities, such as shippers and port authorities
- Agents of concern for emergency response
- Requests from individuals or organizations

Through the nomination process, criteria must be submitted by requestors to substantiate the basis for the request (e.g. exposure, transport, and data availability) that will be considered to move various candidates through the hoppering process.



6.1 Bin 1

The Bin 1 list, or *Agents of Interest*, includes priority agents for potential establishment of one or more guide values. Bin 1 agents are selected from the pre-bin hopper using a filtering process, managed

by the Cross Functional Review Team based on the following considerations, which are expected to be provided in the original nomination request for a guide value:

- Potential for the agent to be released and generate significant exposures (inhalation, oral, dermal) to workers, emergency response personnel, or the community
- Potential for significant adverse health effects (acute to chronic) from inhalation or dermal exposure (These agents can include, but are not limited, to potential carcinogens, genetic toxicants, reproductive toxicants or those that can cause significant and/or irreversible effects to organs or organ systems or significant irritation or discomfort)
- Chemical or biological warfare agents or agents of concern based on possible release from terrorism events
- Availability of a regulatory or guide value by a credible organization

6.2 Bin 2

Bin 2 agents, *Agents under Investigation*, are selected from the Bin 1 agents through a second filtering process using a ranking methodology resulting in a matrix of data to be used for prioritization. Specific filter considerations may vary for each type of guide value but can include:

- Readily identifiable hazard information available from existing published hazard classifications, hazard information data bases, or structural or functional similarity to other chemicals with such data including human and animal data related to the systemic toxicity of the agent by a route of exposure (e.g., inhalation, ingestion, contact)
- Readily identifiable information on exposure potential from existing exposure or chemical use databases or from modeling approaches
- Anecdotal evidence of hazard potential or risk
- Existence of stable chemical markers in biological media like urine, blood, and breath that are related to the internal dose of the agent or its adverse effects by any route of exposure, preferably in a workplace setting, along with sampling and analytical methods for those chemical markers

6.3 Bin 3

Agents with data sets adequate to establish a guide value are moved to the Bin 3 list, *Pending Author Assignment*, while the agents with marginally inadequate data sets remain on the Bin 2 *Agents under Investigation* list.

Agents with inadequate data sets are either maintained on the Bin 2 list or are moved back to the Bin 1, *Agents of Interest* list depending on the nature of the incomplete data set and the uncertainty in the guide value that will result.

Requesting stakeholders are informed if a guide value cannot be established due to a marginally or incomplete data set. The agent is re-prioritized for guide value development when additional data are available.

The Cross Functional Review Team:

- Requests a literature search for those agents with the highest concern to determine both the need for a guide value and the availability of scientific data to establish the guide value, the Guide Rationale and/or the Technical Support Document
- Works closely with the Volunteer Group members, requesting a review of the pertinent literature and a recommendation regarding the adequacy of the data
    - The weight-of-evidence approach is used to assess the adequacy of the data for any particular guide value
- Makes a decision regarding the adequacy of the data set for establishment of a guide value and promotion to Bin 3 (See Appendix B for additional information regarding data adequacy)
- Requests that agents under consideration for a WEEL with adequate or marginally inadequate data sets be assigned to a preliminary WEEL "Health Hazard Band" by a Volunteer Group established for Health Hazard Banding to assist the occupational health professional with exposure guidance until a guide value can be established.
    - The Health Hazard Bands are also used as a tool by the WEEL and BEEL Volunteer Groups in prioritizing guide value development.

6.3.1 Prioritizing Agents in Bin 3

The Bin 3 list, or *Pending Author Assignment*, is unique to each Volunteer Group and includes agents that appear to have sufficient data for establishing guide values. Agents with adequate data sets are prioritized for guide value establishment by each Volunteer Group following their specific procedures. They are prioritized by the Chairperson in consultation with the Volunteer group for assignment to authors. Author availability, expertise and interest as well as potential conflicts of interest influences prioritization of Bin 3 agents for guide value development. The overall prioritization scheme is designed to reasonably apportion the work of the Volunteer group(s) between new recommendations and revisions to existing limits and agents of special interest. The Bin 3 list of agents *Pending Author Assignment* is published on the AIHA website and is updated at least semi-annually.

6.3.2 Assignment to Author/Reviewer: Volunteer group chair assigns agent to an Author and Reviewer(s).

6.3.3 Stakeholder Outreach

- A "Notice of Intent" is published on the AIHA website, indicating that a guide value is in progress.

- Interested stakeholders will have at least three months from the time of publication of the "Notice of Intent" to indicate their intent to participate in the process and notify AIHA that they plan to participate in the guide value development.

NOTE: An approximate timeline is established, based on urgency of guide value establishment and availability of Author. Since the establishment of guide values relies on the support of expert volunteers, strict timelines will not be established.

7 Drafting Guide Values

7.1 Data Search, Retrieval and Archive

The objective of the data search is to compile and review *all* available scientific data, published and unpublished, pertinent to setting the guide value. The type of data, and emphasis placed on each type, varies for the different Volunteer Groups as described in Volunteer Group procedures. The Author (with help as appropriate from other Volunteer Group members or AIHA staff) identifies producer(s), major users and associated industry organizations. On request by the Author, the AIHA requests unpublished data.

7.1.1 The Author (with help as appropriate from other Volunteer Group members or AIHA staff) searches AIHA archives to determine the availability of recent (within 2 years) literature search results.

7.1.2 The Author (with help as appropriate from other Volunteer Group members or AIHA staff) conducts or out-sources literature searches to supplement existing data, as needed. Searches are conducted using the resources and databases as described in the Volunteer group procedures.

7.1.3 The Author (with help as appropriate from other Volunteer Group members or AIHA staff) archives literature search strategy and results so it is available to other Guide Value Volunteer groups.

7.1.4 When possible, original references in electronic form are obtained that are to be quoted in the Guide value Rationale. Under some circumstances, secondary references are permissible for the Technical Support Document.

7.1.5 References are archived.

7.2 Guide Value Derivation

NOTE: Guide values do not provide universal protection. Sensitivity reactions, idiosyncratic reactions, and pre-existing illness may result in adverse effects despite adherence to the guide values.

The objective of the guide value determination is to derive a numerical value based on the principle that human exposure to an agent is not likely to cause harm in most individuals if exposure is maintained below the dose-response threshold, for the most sensitive adverse effect of interest, or is maintained such that the risk at low doses is minimal. This principle allows for the determination or estimation of a point of departure [often a no-observed-adverse-effect-level (NOAEL), lowest-observed-adverse-effect-level (LOAEL), or benchmark concentration (BMC)] for the most sensitive endpoint (i.e., the critical effect). This point of departure is the starting point to which factors are often applied to account for uncertainties in the extrapolation from the available study to a sub-threshold concentration in the population of interest.

The derivation of a guide value for an agent is based on the weight of evidence and classical risk assessment methodology. Applying the weight of evidence approach relies heavily upon professional judgment and reflects an overall, collective assessment of all existing data. Although the general principles noted above apply, the specific procedures for deriving guide values differ for each Volunteer Group since their intended applications differ. Additional information on the methods used by to establish WEELs, BEELs, and ERPGs are provided in the specific procedures for each Volunteer Group.

Robust human health effects data are preferred for developing guide values. In the absence of adequate human health-effects data, a default assumption is typically made that the most sensitive, or critical endpoint in the most sensitive species can be used as the basis for the point of departure. However, data on relevance to human responses and to the scenarios of interest applicable to the guide value specifications are also considered in the overall weight of evidence.

Current occupational risk assessment methodologies apply uncertainty factors to this point of departure for the critical endpoint in calculation of a guide value. The criteria for WEELs, BEELs and ERPGs will vary since a basic assumption behind the rationales for ER values allows for thresholds above minor irritation, severe irritation and up to the threshold for lethality, including irreversible and severe health consequences. Moreover, the underlying assumptions about affected populations and the exposure scenarios of interest vary.

Emergency Response Planning Guideline Values are primarily based on acute and subacute toxicology data sets for inhalation (LOAELs, LC50 values, RD50 values), acute lethality data from other exposure routes (oral, dermal and intraperitoneal injection LD50 values), skin corrosivity and irritancy studies, sensitization studies (respiratory and dermal). Anecdotal and human experience with exposures balances the uncertainties of animal toxicology endpoints, and is the source for ERP-1 levels where irritation or odor awareness/recognition is the primary basis. Subchronic and chronic animal data, along with epidemiological data are also considered to set ERPGs, although these data are not critical as they would be to set an OEL. The subchronic and chronic data are used for perspective on the dose response curve for periods longer than 1-hour exposures. Cancer data is reviewed, but are only included in setting ERPG levels when the risk of developing cancer from a single exposure at a given concentration for the ERPG-2 level would exceed the risk of 1 in 1 million.

For more information on the derivation of WEELs, BEELs and ERPGs, including 'adequate vs. inadequate data criteria', Klemisch data/study scoring, margins of safety, application of Q1* calculations in setting ERPG Values, and Bench Mark Dose considerations, see the individual volunteer group specific AOP.

7.3 Guide Value Preliminary Review and Documentation

7.3.1 Author shares with Reviewer(s) for review/approval.

7.3.2 Reviewer(s) checks references and data used for development of draft guide value and provides feedback to author.

7.3.3 Author modifies draft guide value or documentation as appropriate and submits to Reviewer(s) for a final review prior to the review by the full volunteer group and stakeholders.

7.3.4 The author drafts the Guide Rationale using the appropriate format. The Guide Rationale documents the basis for the draft guide value and includes relevant references.

7.4 Full volunteer group review

7.4.1 Following approval of the draft Guide Value by the Reviewer(s), the draft Guide Rationale is re-submitted to the Volunteer Group Chair for review by the Full Volunteer Group.

7.4.2 Stakeholders and interested AIHA members may attend the volunteer group meeting slated to review the draft Guide Rationale and Technical Support Documents. They are also encouraged to share additional data with volunteer group to either support or modify the guide value.

7.4.3 Draft guide values are modified based on input from voting volunteer group members and comments from stakeholders and interested AIHA members.

7.4.4 Volunteer Group votes to make document available for public review and comment and vote to 'go to ballot' by the volunteer group membership.

7.4.5 Move "draft" guide value to "preliminary" guide value.

8 Balloting/Public comment on preliminary guide value

In order to expedite the process for providing guidance documents, volunteer group balloting and public review period are completed concurrently.

8.1 Volunteer Group Balloting

The "preliminary" guide value is sent to the full volunteer group for ballot. Each full member of the Volunteer Group has the votes on the preliminary Guide Rationale and Technical Support Document within 45 days. The vote options are: abstain, negative, affirmative, affirmative with comments. The preliminary guide value requires affirmative votes by the majority of the full volunteer group members

to pass. All negative votes and affirmative votes with comments are provided to the author for consideration. The author makes revisions to address the comments of the full volunteer group and documents resolution of substantive (non-editorial) changes. The revised preliminary guide value, Guide Rationale and Technical Support Document, reference package, and disposition of comments are sent to the QA/QC Coordinator who ensures the draft guide value, the Guide Rationale, and the Technical Support Document are complete and meet the QA/QC requirements and internal Volunteer Group balloting or re-balloting is completed. Negative votes are addressed by the primary author and revisions to the documents are completed, as needed.

8.2 Public Review

Preliminary guide value(s) are posted to aiha.org and published in Synergist to open 45 day public review period. At the end of the public review period, comments are reviewed by the Author and Reviewer(s) to determine whether modifications should be made to the Preliminary guide value and Technical Support Document. The Author responds to each comment. The comments and responses are archived by AIHA. After comments from the public review are addressed, and if modifications are significant and substantive (that is, they would change the proposed /preliminary guide values), the modified Preliminary guide value supporting documents are returned to the Volunteer Group for reballoting following revisions.

8.3 Final Review

The Author and QA/QC Coordinator review the draft “final” document for editorial and typographical issues, and the Publication Coordinator ensures the full reference package is available. The final Guide Rationale and Technical Support Document and reference package are prepared and forwarded to the AIHA Central Document Repository.

9 Appeals

Following the receipt of a written appeal, the Volunteer Group Chair and the appellant jointly identify a 3-person appeal panel. Both the Chair and the Stakeholder each identify an appeal panel member. The third member is jointly selected by the Chair and appellant. Three attempts to agree on this third panel member are attempted; if no agreement is reached after three attempts, the failure to reach agreement is communicated to the appellant, the Guide Value Volunteer Group and the Technical Operations Council. The appeal dies due to lack of action. The outcomes of appeals that are deliberated by the Appeal Panel are communicated and posted.

Persons who have directly and materially affected interests and who have been, or could reasonably be expected to be, adversely affected by a decision of the [AIHA Guide Value Organization], or by the lack thereof, shall have the right to appeal actions or inaction of the [AIHA Guide Value Organization], provided that the appellant shall have exhausted the appeals procedures of any relevant subordinate group of the [AIHA Guide Value Organization] prior to filing an appeal.

10 Communicating guide values

- Final guide values will be posted on an AIHA Guideline Foundation web page.
- Guide Rationales and Technical Support Documents will be available from AIHA.

11 Follow up on post-publication comments

- Comments on final guide value are sent to Volunteer Group Chair
- Chair categorizes comments as editorial or substantive
- Comments discussed at next /Volunteer Group meeting and documented in Minutes
- Volunteer Groups' action for substantive comments are addressed in writing to Commenter and archived through the AIHA staff.

12 Periodic Review of Existing WEELs, BEELs and ERPGs

Based on member availability, existing WEELs, BEELs, ERPGs and Health Hazard Bands will be scheduled for review at least every 10 years. More frequent reviews may be scheduled, based on compelling new toxicity data or information suggesting increased exposure potential.

13 Data Archival

All data, including literature search, individual scientific publications used in the final Guide Rationale and Technical Support Document, draft comments, suggestions for guide values, Guide Rationale and Technical Support Document drafts are archived electronically at the AIHA Central Document Repository.

A. Appendix: Definitions

Biological Environmental Exposure Levels (BEELs): health-based values that are the biological equivalent of the WEEL; a warning level to institute investigation of exposure, and a guideline related to stopping worker exposure. BEELs are considered for establishment in tandem with WEELs or to supplement other exposure guide values and those related to skin and/or oral exposure.

The Method BEEL: This is the biological monitoring concentration that is one-tenth ($1/10^{th}$) of the Hygienic BEEL to define the value that must be within the linear dynamic range of the biomarker in its biological fluid for an analytical chemical method for the biomarker.

The Action BEEL: This is 50% of the Hygienic BEEL. It is analogous to an OSHA Action Level. Loss of worker productivity, worker discomfort, or minor, reversible health effects may occur in a small minority of health workers having this BEEL condition but not for most of the healthy workers. The Action BEEL is also protective of workers who are not healthy, and those who are apparently healthy but who are susceptible to the chemical or to the specific chemicals or agents used in the workplace if hypersensitivity and synergisms occur.

The Hygienic BEEL: The Hygienic BEEL is the threshold where loss of worker productivity, worker discomfort or minor reversible health effects may occur in a significant fraction of healthy workers having this BEEL condition. The Hygienic BEEL generally indicates a concentration below which nearly all healthy workers should not experience adverse health effects. The Hygienic BEEL also represents the levels of determinants from all routes of exposure that are most likely to be observed in specimens collected from healthy workers who have been exposed to chemicals or agents to the same extent as workers with inhalation exposure only at the Workplace Environmental Exposure Level (WEEL).

The Removal from Exposure BEEL: The Removal from Exposure BEEL is the threshold to consider for worker medical removal for intensive medical examination and non-exposure until below the appropriate Hygienic level BEEL for an appropriate time period.

Other BEELS: Other BEELS may allow levels to be specified for unacceptable levels of worker discomfort or that may impair safe or productive work; for example, eye and skin irritation, repulsive odor, persistent headache, coughing and nausea.

Emergency Response Planning Values (ERPGs) Health-based guide value concentrations for single exposures to chemicals or agents intended for use as planning tools for assessing the adequacy of accident prevention and emergency response plans, including transportation emergency planning and for developing community emergency response plans.

ERPG-1: The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing other than mild, transient adverse

health effects or without perceiving a clearly defined objectionable odor. The ERPG-1 identifies a level which does not pose a health risk to the community but which may be noticeable due to slight odor or mild irritation. In the event that a small non-threatening release has occurred, the community could be notified that they may notice an odor or slight irritation but that concentrations are below those which could cause unacceptable health effects. For some materials, because of their properties, there may not be an ERPG-1. Such cases would include substances for which sensory perception levels are higher than the ERPG-2 level. In those cases, the ERPG-1 level would be given as "Not Appropriate."

ERPG-2: The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.

Above ERPG-2, there may be significant adverse health effects, signs, or symptoms for some members of the community which could impair an individual's ability to take protective action. These effects might include severe eye or respiratory irritation, muscular weakness, CNS impairments, or serious adverse health effects.

ERPG-3: The maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to one hour without experiencing or developing life-threatening health effects. The ERPG-3 level is a worst-case planning level above which there is the possibility that some members of the community may develop life threatening health effects. This guidance level could be used to determine the airborne concentration of a chemical that could pose life threatening consequences should an accident occur. This concentration could be used in planning stages to project possible levels in the community. Once the distance from the release to the ERPG-3 level is known, the steps to mitigate the potential for such a release can be established.

Workplace Environmental Exposure Levels (WEELs): Health-based values, expressed as either time-weighted average (TWA) concentrations (WEELs or Short-Term Exposure Levels, or STELs) or ceiling values believed to provide guidance for protection of most workers exposed as a result of their occupations.

WEEL: The TWA concentration, measured in the worker breathing zone, for a normal 8-hour workday, 40-hour workweek, for which it is believed that nearly all workers can be repeatedly exposed without adverse health effects. In general, periods of exposure should be followed by 16 hours of no exposure, can be repeated for 5 consecutive days provided the 5-day exposure period is followed by 2 days of no exposure before the cycle repeats. Application of the WEEL to alternative work schedules should consider the nature of the effects of concern and the toxicokinetic properties of the chemical or agent as described in the WEEL documentation.

WEEL STEL: A WEEL STEL is a 15 minute time weighted average concentration that should not be exceeded at any time during a work-day.

WEEL Ceiling: A WEEL Ceiling is the instantaneous concentration that should not be exceeded at any time during the workday to prevent acute adverse health effects or discomfort.

While it is intended that WEELs provide guidance for protection of most workers exposed to these chemicals or agents, adherence to these levels does not guarantee protection of all workers, particularly those with underlying health conditions, which make them unusually responsive to some chemicals or other agents.

Guide Rationale and Technical Support Document: The completed, reviewed and published document that summarizes and supports the ERPG values (ERPG-1, ERPG-2, ERPG-3), BEEL Method BEEL, Action BEEL, hygienic BEEL, and REMOVAL from Exposure BEEL) and WEEL (8-Hr Time Weighted Average (TWA), 15-min Short-Term Exposure Level TWA (STEL), and Ceiling Level) and associated health hazard bands. Guide Rationales and Technical Support Documents are published annually and updated every seven years (or more often if compelling data are discovered).

Health Hazard Band: A framework used to develop occupational hazard assessments in the face of uncertainties caused by limitations in the human health or toxicology data for a chemical or other agent. Health hazard banding presumes it is possible to group together chemicals or other agents into categories of similar toxicity or hazard characteristics. Such banding can guide risk communication and risk management strategies in the absence of robust dose-response information.

Stakeholders: "Stakeholders" are individuals or representatives from organizations or interest groups that have a strong interest in or are affected by Guide Values.

B. Considerations for Determining Adequacy of Dataset for Guide Values

Examples of data that are used in the derivation of a guide value include:

- Acute toxicity
- Irritation/corrosivity
- Sensitization
- Genotoxicity (mutagenicity and chromosomal damage)
- Carcinogenicity
- Reproductive and developmental effects
- Toxicokinetics (routes of absorption, distribution, metabolism, and elimination)
- Structural activity
- Include studies of effects in humans at known airborne concentrations, if available
- Known human experiences and epidemiology

The adequacy of the data for any particular Guide Value is assessed using the weight-of-evidence (WOE) approach. Specific data are emphasized differently depending on the type of guide value being established (see Table). WEELs and BEELs for example would typically not be established based solely on acute data, while ERPGs would typically not be set solely on chronic data. But a robust data set would include quality studies for the acute endpoints and subchronic endpoints for ERPGs and subchronic and chronic endpoints for all of the Guide Values

Guide Value Data Criteria Matrix			
Criterion	WOE Value for ERPG?	WOE Value for BEEL?	WOE Value for WEEL?
Acute toxicity (Rat inhalation LC50)	Highly Desired 0.5-, 1-, or 4-hr	Helpful	Helpful
Acute toxicity (Rat oral LD50)	Helpful	Helpful	Helpful
Sensory irritation (RD50)	Desired	Helpful	Helpful
Skin or eye irritation	Highly Desired	Helpful	Helpful
Irritation threshold (ppm)	Desired	Helpful	Desired
Target organ toxicity effect level (e.g., NOAEL, LOAEL, BMD)	Desired	Highly Desired	Highly Desired
Toxicity from repeated-exposure studies by inhalation route (qualitative evidence)	Helpful	Desired	Desired
Severity of target organ toxicity	Highly Desired	Desired	Helpful
Reproductive or Developmental Toxicity effect level	Helpful	Helpful	Highly Desired
Reproductive toxicity (qualitative evidence)	Helpful	Helpful	Desired
Developmental toxicity (qualitative evidence)	Helpful	Helpful	Desired
Genetic toxicity	Helpful	Helpful	Helpful
Cancer bioassay or tumor mode of action data (qualitative evidence)	Helpful	Desired	Desired
Carcinogenicity dose-response	Helpful	Highly Desired	Highly Desired
Other specialty studies (e.g., neurotoxicity or immunotoxicity) or mechanistic information	Helpful	Helpful	Helpful
Warning properties / odor	Highly Desired	Helpful	Helpful
Human Experience – epidemiology, clinical studies, or case studies	Highly Desired	Highly Desired	Highly Desired
Flammability and Reactivity	Desired	Limited value	Limited Value
Toxicokinetics/Toxicodynamics-Human and/or Animal	Desired	Required	Desired
Marker sampling and analytical chemical methods	Limited Value	Required	Limited Value

C. Communicating Draft Guide Values – Recommended Outreach

- Proposed components of a "push" mechanism for making draft guide value manuscript and preliminary guide values available to stakeholders
- Notification will drive interested parties/stakeholders to AIHA web site where they can download/read information
- List of current, pending and "under consideration" chemicals
- List of "due for review" chemicals
- Need to determine groups: do we include academia, government entities, consumers/general public or others as stakeholder groups we need to reach?
- Develop list of stakeholders
    - Contact ANSI, ASTM and other SDO, accrediting bodies for assistance in developing stakeholder list
    - Always notified
        - Larger trade organizations like NAM, ACC, and SOCMA
        - Labor
        - ASTM, ASSE and other SDOs working on related standards
        - Related OEHS associations/professional membership organizations – ASSE, A&WMA, NEAM, etc.
        - Standard development coordinator or other identified individual within CESSE organizations (150+ engineering and scientific associations including IEEE, ASSE, ANSI, ASTM)
    - Notified when chemical of interest is under consideration
        - Manufacturers
        - Key distributors
        - Key end users
    - Identify person and/or mechanism to disseminate information
        - Staff to work to ID specific contact points – standards manager, publications calendar staff person, etc.
        - Post notice on AIHA website and publish in AIHA print and eNews media
        - Make information available electronically at no charge, but need to contact staff to obtain information so we can track stakeholders

- Longer-term: online “registration” and download to eliminate manual tracking by staff
- Develop mechanism to allow persons or groups to “self-register” as a stakeholder
- Track email notifications by AIHA to stakeholders, including bounce and read receipts to be able to monitor reach, gaps, and responses

D. Process Flow Diagrams