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AIHA
ERP Committee

Procedures and Responsibilities

Procedures and Responsibilities
of the AIHA ERP Committee
are always open to comments,
changes and revisions.

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ERPG "Procedures and Responsibilities"

- Defines ERPGs
- Explains How to Author an ERPG Manuscript for Review By the ERP Committee
- Explains the ERPG Review Process
- Defines Responsibilities of ERP members and Officers
- Provides a Template Illustrating the Format of ERPG Documents

Contents

Procedures and Responsibilities
AIHA ERP Committee Members and Officers

Introduction

Emergency Response Planning Guidelines (ERPGs) were developed for emergency planning and are intended as health based guideline concentrations for single exposures to chemicals. These guidelines (i.e., the ERPG Documents and ERPG values) are 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. The emphasis is on ERPGs as ***planning*** values: When an actual chemical emergency occurs there is seldom time to measure airborne concentrations and then to take action.

ERPGs can be used to develop emergency response action plans, including mitigative steps, protective actions, administrative controls such as inventory reduction, and others. Emergency response plans will vary depending upon factors such as population density, type of population (e.g., schools), terrain, weather conditions, and the nature of the release.

ERPG Definitions

The AIHA ERP Committee has utilized three guidance concentration levels. Each of these levels is defined and briefly discussed below:

> 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.

> 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-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 he 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."

It is also possible that no valid sensory perception data are available for the chemical. In these cases, the ERPG-1 level would be given as "Insufficient Data."

Sources of ERPG Documents

Draft ERPG documents may be submitted by individuals, federal and state agencies, organizations, manufactures, responders, countries or any group desiring a peer-reviewed ERPG. These documents may be submitted to the ERP Committee Chair for preliminary review. Where an ERPG is needed but expertise to develop a draft document is not available, a letter submitted to the ERP Chair requesting development of values, and the basis for the need will be considered. Draft ERPG manuscripts should meet the criteria described in **ERPG Authorship, Submission and Review Procedure** (below).

ERPG Authorship, Submission and Review Procedure

When only a request for ERPG values is submitted as described above, or when the Committee is updating an existing ERPG document, the “First Reviewer” also serves as the “Author.” When a draft document is submitted the following procedures must be followed:

1. The authoring organization should use a multi-disciplinary team including industrial hygiene, toxicology, medical and other health professionals to collect and review data, and to develop draft ERPG documents.

2. The author should identify producers, major users and industry associations having a significant interest in the chemical and should request unpublished data

and other relevant information from them. Studies of effects in humans at known airborne concentrations are especially useful. Animal toxicity data are essential.

3. A comprehensive literature search should be conducted and should include appropriate on-line databases such as MEDLINE or TOXLINE. The literature search should be provided with the draft manuscript.

4. The author should make every effort to obtain the original reference for all data because there are frequently errors, interpretations or significant omissions in secondary references.

5. The ERPG Documentation (i.e., the draft ERPG manuscript) should be drafted using the format outlined in Appendix I.

6. The authoring company or organization should submit the draft ERPG Document, marked "Preliminary Draft," to the ERP Committee Chair.

7. Copies of all the referenced literature must accompany the Preliminary Draft document. For some lengthy publications, such as NTP chronic studies, the full referenced item may not be needed. Unpublished, confidential company reports should not be used as references unless at least a summary containing some details of the methods, results and conclusions is provided and it is formally released for use in ERPGs. The use of anecdotal reports is discouraged.

8. The ERP Chair (or designee) will perform a cursory review of the draft ERPG manuscript. If the manuscript is not suitable, the ERP Chair (or designee) will communicate the deficiencies to the author.

9. If the manuscript is suitable, the AIHA ERP Committee will assign a First and a Second reviewer. They will review the draft ERPG in depth and work directly with the author for any necessary clarifications or corrections, as well as ensure all references are in hand and correctly cited. As noted above, when no document has been submitted to the Chair the 1st Reviewer is the Author.

10. Only after this initial review and revision by the First Reviewer will the draft ERPG Document be presented to the full AIHA ERP Committee for a detailed discussion of the data summary, ERPG values, and rationales.

11 If a responsible individual requests the opportunity to attend a Committee meeting to discuss a specific document, the Chairman may, at his discretion, grant permission. The individual should be encouraged (but is not required) to first submit comments in writing. The Chairman has the right to limit discussion as would be necessary to assure an orderly, productive meeting.

- All requests to attend ERP Committee meetings, and all comments not presented at a meeting, must be in writing.
- Written responses (possibly brief) will be given to all written comments by the ERP Chair in discussion with the author and the reviewers.

- Although the Committee may elect to incorporate new information based on these comments, they are under no obligation to do so.

12. A majority vote of members in attendance is needed for Approval to Ballot before sending the final draft to all members for Ballot. Members may vote "yes, "no, or "abstain" on the Ballot. "No" votes must be accompanied by a specific explanation. Two-thirds of the non-abstaining votes received are needed for approval of the ERPG. However, whenever negative votes are cast, an attempt is made to resolve the concerns of the member(s) voting negatively.

13. The committee approved values and justification are then posted on the AIHA website (www.aiha.org). The values are posted for a minimum of 45 days for public comment before being sent to ballot. Comments are sent to the Chair.

14. After a document has been balloted, approved and comments reconciled, the reviewer will send the complete package to the ERP Secretary for submission to the AIHA. The package will include hard copy of the final ERPG document, all references, and an electronic version of the ERPG document.

15. Following approval, the ERPG Document is sent to the AIHA headquarters for publication.

16. Following publication, the ERPG Document is filed at AIHA along with copies of all the referenced literature. These may be made available to the public, as appropriate.

17. ERPGs can be reviewed and revised as relevant new data become available. ERPGs are automatically updated every seven to ten years to maintain Document quality.

18. Drafts of documents may be given out if requested, however, these must be stamped DRAFT on every page. Draft documents will not be published since this could perpetuate incorrect information (which would be corrected during the review process).

19. ERPG values which have not been approved by ballot by the Committee must not be published. These draft values may change as data are reviewed and premature publication could lead to improper citation of ERPG levels. Unless the ERPG has been finalized, the tentative draft values should be removed from any ERPG sent to a non-Committee member for review and comment since these do not reflect the Committee's or AIHA's position. The draft values may be communicated verbally, but with the caveat that they are only tentative.

20. The Emergency Response Planning Guidelines Preface, distributed with the AIHA ERPG Document Set binder, is shown in Appendix II.

21. A Glossary of terms used in ERPG Documents is published annually in the ERP/WEEL Handbook.

ERPG Document Review Criteria

ERPG Draft Documents will not be formally reviewed by the ERP Committee unless the following criteria have been met:

- The draft ERPG conforms to the ERPG Document Format illustrated in Appendix I.
- The ERP Chair (or designee) has performed a preliminary review of the draft ERPG manuscript and found it to be suitable for formal review by the ERP Committee.
- The complete set of supporting references has been received by the ERP Committee Chair.

After the above conditions have been satisfied, the draft ERPG manuscript will be assigned to an ERP Committee member who will serve as the First Reviewer. The ERPG Review Process is depicted in Figure 1.

ERPG Document Update Procedure

Start Update process at ERPG document age 7 years, sooner as needed. Update consists of literature review (include last year of previous review) and evaluation of relevance of new data to the existing ERPG values. Reviewer presents recommendation on whether full committee review is needed and committee votes on recommendation. If ERPG values are reconsidered or major revision needed, follow standard review procedures including ballot process. If major revisions or committee review are not recommended, add new relevant data to document for updated publication. The Update draft will be presented to the committee for comments/approval by voice vote. Copies of any new references will be sent to AIHA ERPG file prior to publication of the updated ERPG. Chair assigns ERPG Update documents to reviewers. Publish ERPG Update document ASAP after review but each document to be updated by age 10 years maximum. The ERP Committee will work with the AIHA staff on scheduling and other aspects of the update publication process.

Responsibilities: ERP Committee Chair

In conjunction with the ERP Vice Chair and the ERP Secretary, the ERP Chair sets the agenda for meetings.

The ERP Committee Chair acts as Chairman of ERP Committee meetings and ensures effective and efficient meetings with a friendly format and a productive atmosphere.

The ERP Committee Chair should, in conjunction with the ERP Vice Chair and the ERP Secretary, work as needed with First or Second Reviewers on documents to identify problems and to help facilitate the resolution of their completion.

The ERP Chair should screen potential documents for ERP Committee review so that documents which have not been adequately reviewed by the First Reviewer do not become an inefficient use of meeting time.

The ERP Chair should maintain and encourage enthusiasm and a path forward regarding the completion and status of documents.

The ERP Chair, when setting the ERP Meeting Agenda, may allocate estimated time limits for durations of discussion of certain topics. For efficiency, the ERP Chair should schedule that certain business-keeping items (review of the minutes, status of related activities) be limited to a brief summary that could be presented by the most qualified party. The interested party should submit a brief summary of their remarks to the ERP Secretary (for inclusion in the minutes) rather than take up document development time at the meeting.

The ERP Committee Chair should actively pursue the participation of new agencies in the ERPG process. This could include new chemical companies based in the U.S. or Europe, academia, governmental agencies in the U.S., Europe, the Far East, or other international groups with an interest in developing and using ERPGs.

The ERP Committee Chair sets the annual AIHA ERP Committee budget in conjunction with the AIHA Board and submits the annual Committee report.

The ERP Committee Chair should issue to the ERP Committee a request for candidates for the three ERP officer positions (ERP Chair, Vice Chair, and Secretary) during the final year of his/her tenure.

Responsibilities: ERP Vice Chair

The ERP Vice Chair should be prepared to conduct the meeting in the absence of the ERP Chair.

The ERP Vice Chair should, in conjunction with the ERP Chair and the ERP Secretary, work with First or Second Reviewers on problem documents to identify potential problems and to help facilitate the resolution of their completion.

The ERP Vice Chair (or his/her designee) along with AIHA staff is responsible for coordinating the logistical arrangements for the ERPG meetings. Meeting arrangements should be transmitted to the ERP Secretary (so that this information can be included in the Draft ERPG Minutes that are sent out by the Secretary within two weeks of each meeting). It is not necessarily the Vice Chair's responsibility to make the logistical arrangements. It is the Vice Chair's responsibility to make sure that meeting arrangements are made and sent to the ERP Secretary for timely distribution to the ERP Committee.

The ERP Vice Chair (or his/her designee) is responsible for identifying, adding, modifying or deleting terms and definitions to the ERPG Glossary (that appears annually in the ERPG Handbook) subject to ERP Committee discussion and informal approval.

It is the responsibility of the ERP Vice Chair (or his/her designee) that, at least annually, the ERP Committee should present a Professional Development Course (PDC), give a presentation, or write a significant paper which identifies the accomplishments of the ERP Committee and keeps the activities of the ERP Committee in the focus of the public eye.

The ERP Vice Chair is responsible for working with AIHA Support Staff to regularly publish the ERP active chemical list in order to solicit outside comment from interested parties. Chemicals under consideration by the ERP Committee should be published quarterly in either the Synergist and/or the AIHA Journal.

- For chemicals where ERPG levels have been approved by ballot, the values will listed on the AIHA Website for 45 days for stake holder and public comment.

- The following statement (or similar) would be included: "The following materials are currently being studied for future ERPGs. Information and comments are welcome. If you have any input on candidate or completed ERPGs, contact ... (Secretary or other individual designated by the Chair). Comments should be submitted within 60 days of the publication of this notice to allow for consideration at our next meeting."

- The designated individual (to whom comments are sent) will direct them to the primary reviewer with a copy to the secondary reviewer and the Secretary. The primary and secondary reviewers will develop

a response, and, with the concurrence of the Chairman, they will send the response directly to the individual submitting the initial comment.

- Copies of both comments and responses will be maintained with the reference packages for the specific ERPG documents. When possible, responses should be made within 30 days following the next Committee meeting.

Responsibilities: ERP Secretary

The ERP Secretary generates minutes of each meeting and circulates Draft minutes to all Committee members within two weeks of the meeting. Members can return any remarks on those minutes to the Secretary within two to three weeks. The ERP Secretary revises the minutes and issues Revised ERP Minutes for brief discussion and vote to accept at the next meeting.

The ERP Secretary summarizes the action items resulting from the ERP meeting, particularly with respect to manuscript review, and includes them in the minutes.

The ERP Secretary should, in conjunction with the ERP Chair and the ERP Vice Chair, work with First or Second Reviewers on problem documents to identify roadblocks and to help facilitate the resolution of their completion.
The ERP Secretary prepares the documents that have been Approved to Ballot and sends Ballots (including the document) to all ERP Committee Members.

The ERP Secretary sets a time frame for return of Ballots in order to allow members time to carefully deliberate, comment, and vote on the Ballot. Generally, the minimum time allowed for return of Ballots will be three weeks. The ERP Secretary will send reminders (phone calls, e-mails, faxes, or other) to members who have not returned their Ballots in time.

Regardless of the results of a Ballot, the ERP Secretary, having received all Ballots and Ballot comments, will forward Ballots and Ballot comments to the primary reviewer of the document so that the reviewer can reconcile dissenting votes and/or affirmative votes (with minor comments) into a final document.

The ERP Secretary will make an archival copy of the final document and all references and then will send the original ERPG package to the designated responsible party at AIHA. The cover letter for transmission of the ERPG document to the AIHA will cc: the ERP Chair, Vice-Chair, and indicate the reviewer as the individual to whom specific questions should be addressed.

The ERP Secretary will maintain the ERPG Active Status List as an Appendix to the Minutes. This Active Status List will be updated at each meeting and included with all minutes.

The ERP Secretary will maintain the ERP Member Roster including names, titles, addresses, phone, fax and e-mails as an Appendix to the Minutes. The ERP Member

Roster will be updated at each meeting and included with the minutes.

Selection and Succession of ERP Committee Officers

The ERP Committee Chairman consults with the ERP Vice Chair and ERP Secretary in nominating committee officers. The AIHA Board Coordinator and AIHA staff liaison may also be consulted. The ERP Officers compose a ballot from the nominations and present a slate of candidates for ballot to the ERP Committee. The ERP Chairman presents the ERP Committee recommendations to the AIHA president-elect as part of the annual ERP Committee roster report. The terms of office for the Chairman and Vice Chair are three years and at least two years for the Secretary to allow for continuity in the development of the ERPGs.

Members and Associate Members of the Committee

Members of the ERP Committee cast one vote in the balloting of ERP Documents or other proposed Committee actions. Members are expected to attend meetings on a regular basis and participate as outlined below in the section on "Responsibilities of ERP Committee Members." Associate members are non-voting members and are asked to advise the Committee and participate in meetings as requested. They may be previous members of the Committee or individuals with specialized knowledge or experience that is helpful to the Committee fulfilling its responsibilities. Associate members are not required to complete the "Committee Conflict of Interest Policy" shown in Appendix V. Even though they are not required (as are full members) to be members of AIHA, they are encouraged to join AIHA.

Responsibilities of First Reviewers

The First Reviewer should carefully read the draft ERPG and work with the author to revise the draft ERPG document, prior to initially presenting it to the ERPG Committee. As previously noted, the First Reviewer may also be the Author.

If the review is to be an Update of an ERPG, it is the responsibility of the First Reviewer to request (from the AIHA) the reference package and an editable electronic copy of the ERPG. The Update package request shall be made in writing and sent to the AIHA Scientific Affairs Assistant and cc: the AIHA Scientific Affairs Associate (see Appendix III, update Request Example).

It is the responsibility of the First Reviewer to revise the document and bring the revised version back to the ERPG Committee.

The First Reviewer Prepares the first draft of an ERPG document in accordance with format guidelines. Drafts should contain page numbers, consecutive line numbers, and the word "draft" on each page. It is suggested that for draft documents, reference citations in the narrative of the document use an author code (e.g. SUS99) rather than a reference number. This will facilitate later technical reviews and reference shuffles.

The First Reviewer Provides an in-process ERPG and copies of all key references to the secondary reviewer for review and comment. The First and Second Reviewers should have completed their reviews before the document is discussed by the full Committee.

The First Reviewer directs and facilitates initial review of the draft document. The purpose of the initial review is to provide a status report on progress, to provide an overview of some of the critical scientific and technical issues that will affect decisions for the values, to identify missing data and references, and to discuss suitability of the data, etc. No ERPG values should be suggested at this time and no line by line reading of document should occur at this time! Requests for sources of additional and more current references from committee members should be made.

The First Reviewer shall present the document to the ERPG committee. The First Reviewer should be prepared to discuss the document and have key references available at the meeting in case clarifications are needed. The purpose of the first committee review is to confirm that the Draft ERPG Document has been reviewed by the First Reviewer. The first review allows the Committee to identify significant deficiencies in the document that need to be resolved before further review can continue.

The First Reviewer shall present a revised document and identify changes made to the previous draft (redline/strikeout). This should be forwarded to ERP committee members prior to the committee meeting when the document with be discussed by the full committee.

When the manuscript has been Approved to Ballot, the First Reviewer will finalize the document for Ballot and send it to the ERP Secretary (who will send it to the Committee for Ballot).

The First Reviewer will resolve issues that may arise during balloting and complete any revisions to the balloted manuscript and reference set.

The First Reviewer will send the entire package (Approved ERP Balloted manuscript, including revisions if any, and all cited references) to the ERP Secretary.

Responsibilities of Second Reviewers

At such time as the Draft ERPG Document has been satisfactorily reviewed and revised under the leadership of the First Reviewer, the Draft ERPG Document (including all references) will be passed to the Second Reviewer.

The Second Reviewer essentially functions the same as the First Reviewer did, however, there may be specific issues with the Draft ERPG Document that were identified during the review process that the Second Reviewer looks into in greater detail. Further there may be experts within the Committee or outside the Committee who should be consulted by the Second Reviewer in order to clarify or confirm certain issues related to the Draft ERPG Document, if this has not previously been done by the First Reviewed.

Either the First Reviewer or the Second Reviewer may wish to contact manufacturers of the chemical in question and seek additional data which is not presented in the original Draft ERPG manuscript.

The Second Reviewer participates in the full Committee discussion and presents the issues that he or she has addressed. The Second Reviewer works with the First Review to resolve the questions and recommendations raised by the Committee during its discussion of the document. Each Committee discussion of the document should involve both the First and Second Reviewers. The Second Reviewer plays an essential role by ensuring that the document is technically accurate and balanced.

Responsibilities of ERP Committee Members

All committee members before serving on the ERP Committee must review and complete on a yearly basis the conflict of interest policy of AIHA shown in Appendix V.

It is most efficient for the conduct of the meeting, and the time of the committee members involved, if Draft ERPG Documents are circulated in advance of the meeting. This allows the ERP Committee members to review the manuscript in

advance of the meeting.

Objections or criticisms to the Draft ERPG Document should be made, during the meeting or in writing, in a collegial spirit. It is not the intent of the ERP Committee (nor its review process) to create adversarial situations resulting in intractable positions. Rather, the ERP Committee encourages productive discussion from its committee members as well as from interested outside parties.

When Draft ERP Committee meeting minutes are circulated, members are asked to review them and to return any and all comments, changes, additions, deletions, etc. to the ERP Committee Secretary within two to three weeks of receipt of those minutes. This allows the ERP Secretary to consolidate changes into a revised set of ERP Committee minutes (which can be presented, briefly discussed, voted on, and passed at the next ERP meeting). Failure to correct the minutes in advance of the meeting causes unproductive delay of ERP Committee meeting time and obligates the ERP Secretary to generate yet another set of minutes with the corrections.

Members should participate in open discussion of any ERPG manuscript. Particularly during the ERP Ballot process, a number of members vote and attach a significant number of comments regarding changes they feel should be made to the document up for ballot. In some cases these changes are editorial in nature, however, in some cases these changes are significant and represent changes in the ERPG values themselves. To the extent that the proposed changes in ERPG values are the result of a more comprehensive individual review by the ERP member, this is an excellent example of the ERP review and ballot process functioning to bring forth the best ideas resulting in the best ERPG documents. To some extent it has appeared that individuals have not participated in the approval to ballot *discussion* and have not addressed their differences with the proposed values in an open forum. This is certainly their prerogative, however, expressing those differences of opinion at the ballot stage significantly delays the production of the ERPG document since the reviewers must now individually identify and resolve each problem (as opposed to resolving them in open Committee discussion).

Responsibilities of AIHA Scientific Affairs Associate

Upon receipt of the ERPG package for a specific chemical (for any chemical the ERPG package consists of a hard copy of the balloted document including changes, an electronic version of that document, and a copy of all references) the AIHA contact person should verify that all references and all relevant document are in fact contained in the package that has been sent. By doing this the AIHA can immediately identify if references are missing, if CDs or disks are not working properly, etc. Since considerable cost can be incurred by participating agencies (in getting translations, in getting obscure references, in scanning references into CD format), it is more efficient (for the participating organizations) to resolve any regrets from AIHA regarding problems right away rather than waiting to fix things during the annual pre-publication rush.

The AIHA should establish an archival process (e.g., on-line data base) for holding the reference documents for each chemical. The AIHA should ensure that ERPG Documents are available in editable electronic format (e.g., Microsoft Word) of a current word processor. It should be recognized that the lifetime for holding these documents is on the order of magnitude of twenty years given that the optimum review cycle is seven years and that at any time anyone wishes to validate an ERPG document or to update an ERPG document, the AIHA is obligated to make available those references. Some ERPG documents are now in their second update. Further, individual references are often requested by agencies or individuals to support current ERPG values.

For continuity, all correspondence made between AIHA and any member of the ERP Committee, and the reverse (regarding the production or progress of any ERPG document), should also be made to cc: the ERP Chair, Vice-Chair and Secretary. The purpose for this is to avoid decisions made inadvertently by a party of one that could affect the products of the ERP Committee.

Once received, AIHA becomes responsible for the document file. This means that AIHA will provide a copy of the reference package and an electronic copy of the ERPG to the assigned primary author for the revision (Update). Should the document and reference package be lost, AIHA will retrieve new copies of all references and will scan and edit an electronic copy of the published document.

The ERP Committee Document and Reference Archival and Retrieval Process Appendix III and the computerized search and reference processing policy is shown in Appendix IV.

Dissenting Opinions

The ERP Committee attempts to resolve all points of view when reviewing an ERPG Document. The ERP Committee attempts to incorporate all relevant data and points of view in the ERPG Documents it ballots, approves and publishes. The ERP Committee strives for unanimity and will try to resolve dissenting opinions of Committee members whenever possible.

In the event that an ERP Committee member disagrees with the ERPG values, rationales, or any other part of an ERPG Document, and if discussion after ballot has not resolved the issue(s), the ERP Committee encourages the dissenting member to submit a dissenting ERPG Document.

Table 1. ERPG Terminology (A More Complete List of Terms May Be Found in the ERP/WEEL Handbook – Glossary)

AIHA: The American Industrial Hygiene Association.

Annual Document Set: The ERPG Documents, including Updated Documents, that are published annually by the AIHA.

ERP Committee: The Emergency Response Planning Committee of the AIHA.

ERPG Document: The completed, reviewed and published manuscript that summarizes and supports the ERPG values (ERPG-1, ERPG-2, ERPG-3). ERPG Documents are published annually and Updated every seven years (or more often if compelling data is discovered).

ERPG Document Set: The entire collection of ERPG Documents that exist for all chemicals having ERPGs.

ERPG Documentation: Same as ERPG Document.

ERPG Handbook: Formally titled "The AIHA (year) Emergency Response Planning Guidelines and Workplace Environmental Exposure Level Guides Handbook", the ERPG Handbook is published annually by the AIHA.

ERPG Values: The airborne concentrations developed by the ERP Committee to meet the definitions of ERPG-1, ERPG-2, and ERPG-3 for a particular chemical.

Notebook: The entire collection of ERPG Documents, updated annually by AIHA.

Update Document: A previously published ERPG Document which is being reviewed either because of new data or because the Update cycle (typically seven years) has expired.

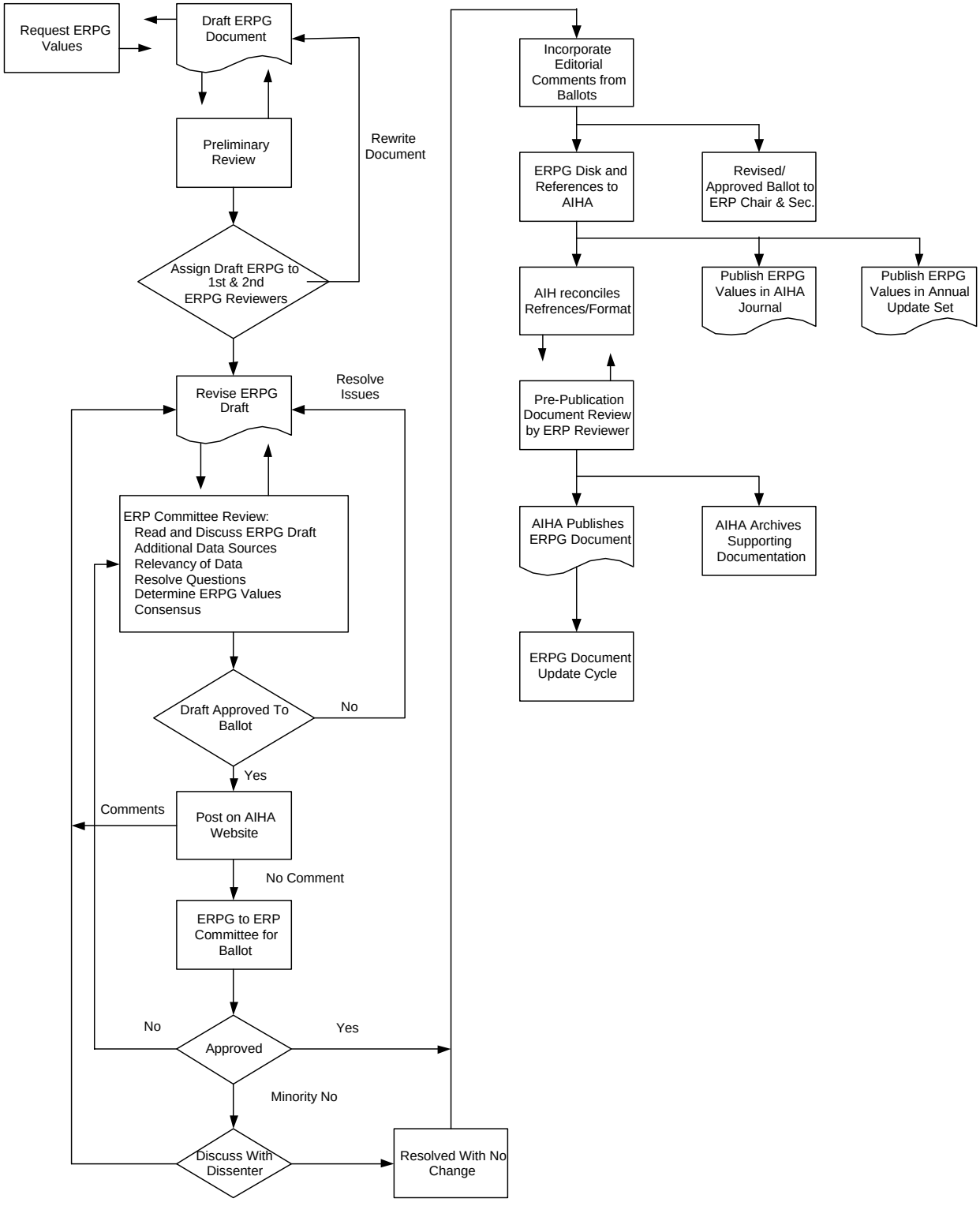

Figure 1 - ERPG Review Process (Flowchart)

Appendix I ERPG Document Format

ERPG DOCUMENTATION FORMAT

Author (optional), _____
Draft Number_____
Date

EMERGENCY RESPONSE PLANNING GUIDELINE (ERPG)

CHEMICAL NAME

ERPG-3:
ERPG-2:
ERPG-1: _____

Original:

date Revised:

date

I. Identification

Chemical Name:

Synonyms: (separate by semi-colon; if using an abbreviation for the chemical name, include it as a synonym)

CAS Number:

DOT: UN _____

Molecular Formula:

Structural Formula:

II. **Chemical and Physical Properties** *(References for this section go here)*

NOTE: Give physical properties at 760 mm Hg and 20-25°C whenever possible.) Physical State and Appearance:

Odor Description: (not thresholds, etc.)

Molecular Weight:

Conversion Factors:	1 mg/m^3 = ppm v/v		
	1 ppm v/v = mg/m^3		
Melting Point:	°C	°F	
Boiling Point:	°C	°F at	mm Hg
Vapor Pressure:	mm Hg at	°C	°F
Vapor Density:			
Liquid Density:			
Specific Gravity:			
Specific Volume (Gas):			
Flash Point (closed cup):	°C	°F	
Flammability Limits:	LEL	UEL	
Autoignition Temperature:	°C	°F	

Saturated Vapor Concentration

Vapor Pressure

Vapor Density

Stability and Reactivity:

Solubility in Water:

III. Animal Toxicity Data

(Note: Summarize each study separately. Give duration, route, species, and the effects at each dose not just the no-effect level. Include negative findings as well as positive. Lengthy detail is unnecessary for some studies judged to be of minimal relevance for establishing an ERPG. When no information is available, retain the subject heading and state "No data available." Several heading may be combined for this purpose.)

A. Acute Toxicity and Irritancy - (include studies of <5 days)

1. Oral - (ex. LD_{50} rats: 100 mg/kg

2. Eye Irritation (or Toxicity)

3. Skin Toxicity

a) Skin Irritation

b) Skin Absorption

c) Skin Sensitization

4. Inhalation Toxicity

(Note: State exposure duration for all LC_{50}s, state whether nominal or analytical concentrations were reported; include pathology, if available, give mortalities at individual doses, not just the $LC_{50,}$ if available; give lowest lethal concentration and highest nonlethal concentrations when available. For easy comparison of data, convert any mg/m^3 units to ppm for all vapors and gases.

B. Subacute Toxicity (5-14-day studies)

C. Subchronic Toxicity (15 -day to 6-month studies)

D. Chronic Toxicity and Carcinogenicity (>6 months)

E. Reproductive and Developmental Toxicity (include teratology and reproduction studies)

F. Genotoxicity/Mutagenicity

G. Metabolism/Pharmacokinetics

H. Other

IV. Human Experience

A. Odor Data (Note: Include odor threshold when available, not just odor descriptions.

B. Toxicity Data (NOTE: Include actual test data (that is, where humans were exposed to known concentrations, not interpretations of animal test data).

C. Workplace Experience

D. Epidemiology (NOTE: A brief summary is sufficient.)

E. Other (NOTE: May include opinions or estimates of human effects which are based only on animal data.)

V. Cancer Risk Calculation (Applicable when appropriate q* data exists.)

An estimate of the potential for a carcinogenic response to short term exposures will be developed based on the Committee on Toxicology, National Research Council (NRC) approach (NRC 1994). The estimate will be developed when a q* slope value has been published by the EPA or when appropriate data are available to calculate a q* value. The estimate from the NRC calculation will then be compared with the health based derived value for the ERPG II. Based on the Committee's assessment of the quality of the chemical's database, the ERPG II value may be replaced by the NRC estimate. The Committee will make the final decision on the scientific appropriateness of the NRC estimate based on the weight of the studies. The NRC estimate will be included in the technical document.

VI. Current Occupational Exposure Guidelines

(Give the source of organization, the guideline number, and a brief statement about the rationale used. Rationales for STEL's or other short-term guidelines are of particular interest).

A. ACGIH TLV or AIHA WEEL

B. OSHA PEL, NIOSH REL

C. NRC EEGL, SPELL

VII. Recommended ERPG's and Supporting Rationales

(Although three ERPG levels are generally set for each chemical, occasionally only one or two ERPG levels will be judged appropriate. For instance, if the odor and irritancy concentrations are higher than the ERPG-2 level, an ERPG-1 value is inappropriate. This section should include the rationales for each ERPG level as well as an explanation for any level omitted).

A. ERPG-3: _____ ppm (_____ mg/m^3)

It is believed that nearly all individuals could be exposed to _____ ppm for up to one hour without experiencing or developing life-threatening health effects. (Add basis for number selected - ex. Most important studies/data, noted effects).

B. ERPG-2: _____ ppm (_____ mg/m^3)

It is believed that _____ ppm is the maximum airborne concentration below which nearly all individuals could be exposed for up to one hour without experiencing or developing irreversible or other serious adverse health effects or symptoms which could impair an individual's ability to take protective action. (Add basis for number selected).

C. ERPG-1: _____ ppm (mg/m^3)

It is believed that _____ ppm is the maximum airborne concentration below which nearly all individuals could be exposed for up to one hour without experiencing or developing effects other than mild transient health effects or without perceiving a clearly defined objectionable odor. (Add basis for number selected). If the threshold is above the ERPG-2 level, it is not appropriate to have an ERPG-1 level and the designation should be "Not Appropriate." If there are no data on odor or mild irritation, then the designation should be "Insufficient Data."

VII. References

- References should follow the format shown in the "Style Book for AIHA Publications."
- Always review and cite primary references whenever possible.
- If secondary references must be used, the reference should state as follows: "(primary reference.) In (secondary reference)."

Appendix II ERPG Preface

Emergency Response Planning Guidelines

The Emergency Response Planning Guideline (ERPG) values are intended to provide estimates of concentration ranges where one reasonably might anticipate observing adverse effects as described in the definitions for ERPG-1, ERPG-2 and ERPG-3 as a consequence of exposure to the specific substance.

> The ERPG-1 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed up to 1 hr. without experiencing other than mild transient adverse health effects or perceiving a clearly defined, objectionable odor.
>
> The ERPG-2 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hr. without experiencing or developing irreversible or other serious health effects or symptoms which could impair an individual's ability to take protective action.
>
> The ERPG-3 is the maximum airborne concentration below which it is believed that nearly all individuals could be exposed for up to 1 hr. without experiencing or developing life-threatening health effects.

It is recognized by the committee (and should be remembered by all who make use of these values) that human responses do not occur at precise exposure levels but can extend over a range of concentrations. The values derived for ERPGs should not be expected to protect everyone but should be applicable to most individuals in the general population. In all populations there are hypersensitive individuals who will show adverse responses at exposure concentration below levels where most individuals normally would respond. Furthermore, since these values have been derived as planning and emergency response guidelines, not exposure guidelines, they do not contain the safety factors sometimes incorporated into exposure guidelines. Instead, they are estimates, by the committee, of the thresholds above which there would be an unacceptable likelihood of observing the defined effects. The estimates are based on the available data that are summarized in the documentation. In some cases where the data are limited, the uncertainty of these estimates is large. Users of the ERPG values are encouraged strongly to review carefully the documentation before applying these values.

In developing these ERPGs, human experience has been emphasized to the extent data are available. Since this type of information, however, is rarely available, and when available, usually is only for low level exposures, animal exposure data most frequently forms the basis for these values. Usually, the most pertinent information comes from acute inhalation toxicity studies that have included clinical and laboratory (functional) observations together with macro- and microscopic examination of organs and tissues. It is important to describe the highest levels not showing the effects described by the definitions of the ERPG levels, whenever possible. Next, data from repeated inhalation exposures, again with clinical and laboratory observations, together with macro- and microscopic examination of organs and tissues, should be considered. Following these in importance are

the basic, typically acute studies where mortality is the major focus. When inhalation toxicity data are either unavailable or limited, data from studies involving other routes of exposure will be considered. More value is given to the more rigorously conducted studies, and data from short-term studies are considered to be more useful in estimating possible effects from a single 1-hr exposure. Finally, if mechanistic or dose-response data are available, these are applied, on a case by case basis, as appears appropriate.

It is recognized that there is a range of times that one might consider for these guidelines; however, it was the committee's decision to focus its efforts on only one time period. This decision was based on the availability of toxicology information and a reasonable estimate for an exposure scenario. Users who may choose to extrapolate these values to other time periods are cautioned to review the documentation fully since such extrapolations tend to hold only over very limited time frames, if at all.

Appendix III Document and Reference Archival and Retrieval

Introduction

This document describes the process to be used by AIHA staff and the members of the Emergency Response Planning Guideline (ERPG) and the Workplace Environmental Exposure Levels (WEEL) Committees to properly archive and retrieve the supportive documentation and associated references for each guideline level produced. *(Actual detailed procedures will be developed, agreed to by AIHA staff and Committee members, and documented to ensure agreement on responsibilities)*

Archival / Retrieval

The multifaceted purposes of this process include, but are not limited to:

- Ensure that actual references exist as cited to protect the liability of the pertinent Committee and ultimately AIHA, especially when "unpublished" data are used
- Original references are available to Committee members during subsequent updates in order to save time, energy, and money
- Save the resources of re-typing the documentation back into MSWord for future editing

Background

Historically, volunteer members have contributed countless hours of work and immeasurable amounts of money in the development of ERPGs and WEELs on behalf of the AIHA. This work culminates in the development of a complete reference technical supporting document and the full citations referenced therein. The understanding by both Committees has been that AIHA staff would properly archive these documents at AIHA headquarters for subsequent retrieval in the future by interested parties and especially by the volunteer members during the 10-year update process.

- An audit of the ERPG and WEEL files reflects that about 50% of the references (overall) are missing from the documentation files at AIHA as of year 2000. These documents were either never submitted to AIHA or were misplaced once they reached AIHA.

Process Overview

It is imperative for authors of ERPG and WEEL guideline documentation to locate, use, and present the best data available to develop guidelines. As part of that data quality requirement, the whole reference is retrieved and reviewed in the documentation. This effort is resource intensive, and so as to preserve the value of this effort, the document and the references must be archived in a document management process which also provides for easy and accurate retrieval.

This process requires each Committee to first QA the document versus references cited, and then provide the MSWord document and all the references (hard copy or electronic) to AIHA headquarters.

AIHA staff shall also perform a QA verification of the cited references and contact the author for missing references prior to publication of the new/updated documentation. In order to facilitate this process according to publication deadlines, Committee members shall follow strict submission dates.

AIHA staff will also convert all hard copy references to electronic format and the MSWord version of the documentation that shall be archived on CD to make available to Committee members for future updates of the document. Since this media can be lost easily, a server storage device, with regular backups and with passwords, may be used as the primary archival/retrieval system. (staff is investigating possibilities)

Each year, a CD of the complete documentation set and references for that year archived shall be provided to Committee members.

AIHA shall provide future authors with a complete documentation package, including previously "missing" references. (Note: AIHA is working with the committee to retrieve all missing references for near-future updates first)

Responsibilities

Archival Process

Responsible:	***Activity:***
Committee Author	• MS Word format documentation • 100% cited references (hardcopy &/or electronic)
Committee Process	• QA that 100% references cited are present and properly cited • Forward to AIHA Publication staff by stated deadline
AIHA Staff	• QA that 100% references cited are present and properly cited • Publish the guideline documentation and supply hard copy set to each Committee member • Convert all hard copy references to electronic format (searchable .pdf) (AIHA does not have the resources to do this) • Archive electronic documentation/references on CD for easy retrieval • Supply CD of MSWord documentation and 100% references for the pertinent year to each Committee member • Archive all documentation and 100% references on a document management server at AIHA for future retrieval (AIHA investigating)

Continued on next page

Responsibilities

Retrieval Process

Responsible:	Activity:
Committee Author	• Contact AIHA staff for electronic version of documentation/references (including MS Word format documentation) for guideline to update
Committee Process	• Inform AIHA staff of upcoming guideline updates to ensure that electronic retrieval of a complete documentation package is anticipated.
AIHA Staff	• Document the Committee request for documentation retrieval • Perform QA to ensure that 100% references cited in past documentation package are present (if not, invoke the "Missing Reference Procedure" lead by AIHA staff prior to sending out package) (What procedure does this refer to?) This should be developed by both Committees with agreement/understanding by AIHA staff (one harmonized process/procedure) • Supply CD of MSWord documentation and 100% references for the requested guideline to the author. This should be done in a traceable process to ensure receipt by the author. (Please clarify "traceable process") [There should be a defined process for the development, archival and retrievable of these CDs which would be available for updates in the future!]… This should be developed by AIHA staff, documented and understood by both Committee memberships and responsible staff.

Appendix IV ERPG Document Search Strategy and Protocol

A comprehensive literature search is implemented for each chemical compound identified by the Emergency Response Planning Guideline Committee. All search requests are forwarded to a specialist best suited to find the information. Once a request is received a strategy is created as described below to search and retrieve relevant reference materials.

The following information search strategy elements will be included for each chemical compound.

- *Chemical Identification*
- *Chemical and Physical Properties*
- *Animal Toxicology Data*
- *Human Toxicology Data*
- *Current Exposure Guidelines*

The focus of the search for the guideline development is toxicity related to short term exposures. Samples of relevant information sources to be searched are listed in Table 1.

All references identified from the search strategy results are reviewed for relevancy. If the hits match the request, the results are then forwarded on to the chemical guideline author. If the results come up with irrelevant information or nothing at all, the specialist then revises the strategy and searches again. We are able to deliver the most relevant results when the client provides details on their request, such as how they will apply the information and the type of information needed (patents, journal articles, government papers, etc.) (see Table 2).

Document Retrieval

References requested from the search strategy results are identified and either retrieved from libraries or accessed databases. The major research libraries around the world will be accessed to obtain new requested articles in a timely manner (see Table 2).

Document Imaging and Database Management

Paper documents are scanned, captured and stored with other digitally retrieved references. We manage a high-speed imaging center. Imaging enables us to quickly and accurately scan, number and link documents to their respective databases, which we also create. Imaging provides quick and easy retrieval of documents in their original format (see Table 2).

- Scan Researched Documents to Digital Text
- Create Searchable Index
- Catalog based on Committee Needs
- Create CD-ROM or DVD-ROM of all retrieved references

Appendix V Relevant Information Sources Examined

- RTECS (Registry of Toxic Effects of Chemical Substances)
- CCRIS (Chemical Carcinogenesis Research Information System)
- HSDB (Hazardous Substances Data Bank)
- GENE-TOX (Genetic Toxicology)
- IRIS (Integrated Risk Information System)
- TRI (Toxic chemical Release Inventory)
- TRIFACTS (Toxic Chemical Release Inventory Fact Sheets)
- TOXNET (Toxicology data Network)
- ChemID (Chemical Identification)
- MEDLINE (Medlars Online)
- TOXLINE (Toxicology information online)
- MEDLARS (Medical Literature Analysis & Retrieval System)
- BIOSIS (Biological Abstracts)
- AEA (Applied Ecology Abstracts in LSC)
- BIO (Biological Abstracts)
- CAB (Chemical Abstracts 1968-date)
- ASFA (Aquatic Sciences & Fisheries Abstracts 1979-date in LSC)
- CSN (Chemical Safety NewsBase 1995-date)
- NIO (Occupational Safety and Health 1950-date)
- TOXA (Toxicology Abstracts 1979-date in LSC)
- HEEP (Health Effects of Environ. Pollutants 1972-date in BIO)
- HEAST (Health Effects Assessment Summary Tables)
- REDs (EPA Pesticide Reregistration Eligibility Decisions)
- EXTOXNET (The Extension Toxicology Network)
- Cal/Ecotox (California Wildlife Exposure Factor and Toxicity Database)
- TOX-ONE (EPA Toxicological One-Liner System)
- EPD2000 (Farm Chemicals Handbook 2000)
- EPD97 (Farm Chemicals Handbook 1997)
- RTC (Registry of Toxic Effects of Chemical Substances)
- NIOSHTIC (National Institute for Occupational Safety and Health)

Appendix VI Committee Conflict of Interest Policy

All ERP Committee Members and Officers are to complete the following Conflict of Interest Policy when they become member of the Committee, as described below:

AIHA Conflict of Interest Policy (Officially accepted by the ERP Committee.)

1. **Policy Statement**. Each officer, director, and committee or task force member ("volunteer leader") should avoid both actual and apparent conflicts of interest that would interfere with their ability to discharge their fiduciary responsibilities to the American Industrial Hygiene Association ("AIHA"). AIHA encourages its volunteer leaders to follow ethical standards, to be in compliance with all laws, and to avoid any conflict of interest, or appearance of such, including having their titles or affiliation used to publicize personal or company activities, programs, or events (especially those conducted for private profit).

2. **Conflict of Interest Defined**. The term "conflict of interest" includes, but is not limited to, circumstances where a volunteer leader, or a member of his or her immediate family: (a) owns any financial or other proprietary interest in any entity supplying (or seeking to supply) goods or services to AIHA; (b) receives any substantial benefit from a third party on account of that party's past, present, or future business relationship with AIHA; (c) receives any substantial financial benefit from a pending decision of AIHA or from an organization or individual being evaluated by AIHA; or (d) serves as an officer, director or committee member of any competing organization, i.e., any nonprofit or business enterprise whose purposes, products, and/or services compete with those of AIHA.

3. **Disclosure of the Existence of a Conflict**. If any volunteer leader of AIHA knows, believes, or has reason to know or believe, that a conflict of interest exists with respect to any transaction involving AIHA, any decision of the Board, any decision of a committee or task force, or any action taken by an officer, such person shall inform the Board or the Committee of the existence of such conflict of interest or potential conflict of interest.

4. **Effect of the Existence of a Conflict of Interest**. In the event that it is determined that a conflict of interest exists, and the volunteer leader has made full disclosure of the facts surrounding the conflict, then the ERP Committee shall determine whether the volunteer leader may fully participate in the deliberations and vote on the proposed transaction. If the volunteer leader merely discloses the existence of the conflict of interest or potential conflict of interest, yet fails to disclose or is prohibited from disclosing all material facts regarding the conflict, then such volunteer leader shall be prohibited in participating in any manner or form in the deliberations or decisions regarding the affected transaction.

5. **Resignation**. No individual who has an actual conflict of interest shall be required to resign his or her position with AIHA merely because of the existence of a conflict. However, the remaining members of the ERP Committee may make a fair and full evaluation of all facts pertaining to the conflict of interest to determine its extent. If the remaining members of the ERP Committee make a determination in writing that the nature and extent of the conflict of interest is so substantial and of such a continuing nature that it would be impossible for the volunteer leader to discharge the duties of his or her office with the requisite degree of loyalty and integrity, then the ERP Committee may require the resignation of the volunteer leader who is subject to the conflict of interest.

Form to be Completed by Committee Members

DISCLOSURE FORM

I have reviewed the AIHA Conflict of Interest Policy and agree to be bound by its provisions for the duration of my appointed or elected term.

Competing organization(s) to which I belong:

Organization(s) that I have a financial interest in that may be affected by my AIHA service:

_____
Name

_____
Title

_____
Date