OPERATIONS MANUAL

THRESHOLD LIMIT VALUES FOR CHEMICAL SUBSTANCES COMMITTEE

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1. COMMITTEE MISSION

The Threshold Limit Value Chemical Substances (TLV®-CS) Committee is a Standing Committee established by the Board of Directors of the American Conference of Governmental Industrial Hygienists (ACGIH®). This Committee's vision is to be a respected, worldwide leader in the development and dissemination of health-based occupational exposure guidelines.

The mission of the Committee is to develop occupational exposure guidelines that are:

- Scientifically credible
- On the leading edge
- Judgment-based
- Well-supported (i.e. TLVs® are based on ACGIH®'s review of "peer-reviewed scientific literature")
- Scientifically valid
- Reliable
- Understandable and clear
- Produced with an honest, unbiased and clearly-defined process

2. MEMBERSHIP

a) Eligibility

Members of the CS-TLV® Committee must be members of ACGIH®. The Committee may have up to 30 members who should represent the four disciplines necessary to establishing TLVs® (industrial hygiene, occupational medicine, occupational epidemiology, and toxicology). No more than 25% of the Committee may consist of Associate members of ACGIH®. However, all members of the Committee will have full voting rights for the purposes of the business of the Committee. (Each member must have participated in the annual conflict of interest declaration and signed an annual conflict of interest statement.) The Committee may utilize consultants, as necessary, for additional specialized and temporary expertise. Consultants do not have voting privileges and attend meetings only at the invitation of the Chair.

b) Member Selection

Anyone interested in joining the Committee will be asked to complete a short application form (Appendix A) and provide a resume or curriculum vitae. The Membership Subcommittee will review the application and determine whether the applicant is eligible and fits the needs of the Committee. This process is described in detail in the Membership Subcommittee section.

The following criteria will be used to evaluate an applicant for membership:

- Disciplinary training and education
- Professional background
- Past relevant experience
- Personal characteristics

The following criteria will be used to assess the overall membership of the Committee and whether a particular applicant fits:

- The Committee should have a mix of persons who have expertise in one or more of the following: industrial hygiene, occupational medicine, epidemiology, toxicology or other related specialties (e.g. statistics, chemistry, etc.)
- A preference will be given for individuals with 10 or more years of professional experience and with advanced degrees in their field of expertise
- Individuals should demonstrate writing capabilities and communication skills through publications, presentations or other activities
- The membership should reflect the demographics of the industrial hygiene and occupational health workforce
- Persons with multi-disciplinary backgrounds and experience are encouraged to apply

c) Member Responsibilities and Expectations

Each member of the Committee (with the exception of the Chair) will be affiliated with one of the Chemical Substance (CS) Subcommittees. Expectations for each member of a CS Subcommittee include the preparation of two TLV® *Documentation* annually; at least one of which should be for a new substance. These expectations may vary for individual members, depending on other activities undertaken within the Committee. Individual members will negotiate their activities with CS Subcommittee Chair, with review by the Committee Chair.

In addition to CS Subcommittee activities, each member of the Committee is expected to actively participate on at least one other Administrative Subcommittee. Chairs of the CS Subcommittees will not be expected to participate in the Administrative Subcommittees due to their workload. Members may participate in more than one Administrative Subcommittee if they wish.

Members are expected to contribute annually approximately four weeks of their time to the work of the Committee. This estimate includes time spent attending four meetings each year; preparing and reviewing TLV® *Documentation*, and participating in Administrative Subcommittee activities. More senior members will also be expected to provide guidance and mentorship to new members.

Members are expected to comply with the Committee's confidentiality guidelines and Conflict of Interest policy. They are expected to interact at all times in a collegial fashion with other members of the Committee and Staff.

Participation on the Committee is a privilege that must be continually earned, through on-going productivity, participation and collegial behavior. When considering re-nomination, the Chair will review a member's participation in light of membership expectations and length of tenure on the Committee. As members serve additional terms they are expected to take on a greater role in the Committee, which may include preparing additional documentations, chairing a Chemical Substance or Administrative Subcommittee, and other activities as needed.

d) Conflict of Interest

The TLV® Committee follows the ACGIH® Conflict of Interest Policy, as described in Appendix F. Members should review all of the details of this policy. Information relevant to the TLV® Committee and its conflict of interest process are described below.

Bias is defined as "views stated or positions taken that are largely intellectually motivated or that arise from close identification or association of an individual with a particular point of view or the position or perspectives of a particular group." Conflict of interest means "any financial or other interest which conflicts with the service of an individual because it (1) could impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization."

In the case of bias, the Committee attempts to create a balance of opinions and views by maintaining a diversity of professional affiliations, disciplines and activities among its membership.

In the case of conflict of interest, the Committee has created a number of avenues for minimizing or eliminating the potential effects of conflict of interest while allowing a member to participate as fully as possible in Committee activities. The Committee believes that it is the primary responsibility of the individual member to identify his/her potential conflicts and to consider carefully the level of participation that is appropriate.

At least once each year, the Committee Chair will conduct a presentation and discussion of conflict of interest with the full membership of the Committee. This presentation will include a variety of scenarios and possible methods for resolving conflicts while maintaining participation. Every member of the TLV® committee will be asked to briefly describe relevant information concerning his/her background, current professional activities, consultancies, financial holdings, research funding, etc. This description will focus on all activities and associations that may have relevance to the activities of the Committee. The TLV® Committee will thus identify for itself and its members any substances or issues that represent a conflict of interest for any of its members.

In addition to the annual discussion of conflicts of interest described above, each Chemical Subcommittee Chair will begin the review of new substances with a request for notification of conflict of interest from the subcommittee members. In addition, any member who develops a new conflict of interest for an ongoing chemical documentation will be encouraged to notify the other members of the subcommittee.

It may not always be in the best interests of the TLV® Committee for a member who has significant conflicts of interest to remove themselves entirely from the development of a TLV® because they may be very knowledgeable about that particular substance. In such cases, the Subcommittee Chair should work directly with a member to assure these conflicts are minimized while allowing for as full participation as possible. Should a member who works for an entity with a direct interest in a substance undertake the initial authorship of a documentation concerning that substance, a variety of paths may be utilized for minimizing the effects of this conflict of interest. These may include:

- assigning a co-author who will review all of the literature and assist in the preparation of the *Documentation*;
- external review by a Committee member who belongs to another Chemical Substance Subcommittee (described in the section on *Documentation*); or,
- external review by an expert external to the Committee (the latter is recommended only rarely).

Committee members who work for governmental regulatory agencies and are directly responsible for the development of exposure guidelines may not author TLV® *Documentation* for substances under the purview of this agency.

Open and free discussion of conflict of interest is key to this process. The classification of conflict and the selection of the appropriate action should not be left to the individual but is based on a consensus of the whole subcommittee. If there is no consensus with the

subcommittee, the appropriate action is at the discretion of the subcommittee chair. The Committee Chair should be informed of all high levels of conflict and proposed action. All conflicts and actions taken should be documented in subcommittee and committee minutes.

To assist in identifying levels of conflict and possible actions for mitigating conflict, the following definitions are offered as guidance.

High Degree of Conflict

A "high" level of conflict exists if a member has been or currently is directly involved with the substance.

Examples of situations with a high level of conflict are:
a. A member working with a regulatory agency who plays a role in developing regulations for the chemical substance.
b. A member affiliated with an academic institution who has performed research central to the TLV®.
c. A member who works for a company that is a major producer and who plays a direct role in the development of internal exposure levels.

In most cases where a high degree of conflict exists, the member should not author the *Documentation*, should not participate in discussions about the recommended TLV®, and should abstain from voting on the TLV®. The member may discuss matters of science and express opinions about individual studies. In some cases it may be possible for the member to participate in authorship of the *Documentation* as a co-author (following full discussion with and approval from the subcommittee and committee chairs); they should not participate in drafting or discussing the TLV® Recommendation or value, however.

Medium Degree of Conflict

A "medium" level of conflict exists if a member has been or is indirectly involved with the chemical substance.

Examples of situations with a medium level of conflict include:
a. A member who works for a regulatory agency that regulates the chemical substance, does not have a direct role in developing regulations but may be concerned with enforcing regulations.
b. A member who works for an academic institution whose research may be concerned with the chemical substance but is not central to the determination of a TLV®.
c. A member employed by a company that is a major producer of the chemical substance but who plays a minor role in the internal development of exposure levels.

When an intermediate level of conflict has been identified, the matter should be carefully discussed with the subcommittee chair and members and appropriate steps taken to mitigate the conflict. Typically this will mean assigning a co-author or a reviewer for the *Documentation*. In some cases, abstention from voting on the TLV® is also appropriate.

Low Degree of Conflict

A "low" level of conflict exists if the member is affiliated with an organization that has a financial or other interest in the substance but has a very minor or nonexistent role with respect to the substance.

Examples of situations with a low level of conflict include:

a. A member affiliated with an academic institution who does not conduct research relevant to the chemical substance but whose immediate colleagues have research that is directly concerned with the substance.
b. A member working for a regulatory agency that regulates the substance but whose role is to provide consultative advice to industries.
c. A member working for a company that is a major producer who has no role in the development of internal occupational exposure levels.

In most cases, simply informing the subcommittee and committee members about low-level conflicts is all that is needed.

All members who have participated fully in the Chemical Subcommittees and full TLV® Committee discussions about conflict of interest and who have made their best effort to eliminate or minimize personal conflicts will be eligible to participate in all votes. In situations where there are high levels of conflict, members may choose to recuse themselves from any discussions and reviews, and must recuse themselves from votes related to that substance.

Failure by any member to report a conflict of interest is grounds for immediate termination of that member's service on the Committee. This decision will be made by the Chair after review and deliberation with the Steering Committee. The Chair will conduct a review with the Steering Committee and make a recommendation to the Board. Depending on the status of the TLV® (under study, proposed or adopted), it may be necessary to carry out a complete review of the decision-making process for the substance to determine appropriate action.

e) Terms

Members serve three-year terms, generally beginning January 1. They may be re-nominated to additional three-year terms, for a maximum of six terms (18 years). The Committee Chair will consult with the appropriate Chemical Substance Subcommittee Chair and other members of the Committee prior to recommending re-nomination.

Expectations for continuing membership (up to two terms or 6 years) include, at a minimum:

- Attending all meetings
- Participating in all scheduled conference calls
- Preparing at least two *Documentation* each year (at least one of which should be for a new substance), and
- Actively participating in at least one Administrative Subcommittee

Expectations for continuing membership (two to five terms or 7-15 years) include, at a minimum:

- Chairing an Administrative Subcommittee or taking on a similar, substantial leadership role and
- Preparing at least three *Documentation* each year (at least one of which should be for a new substance)

Expectations for continuing membership (beyond 5 terms or 15-18 years) include:
- Taking on a leadership position in the Committee – Committee Chair, Committee Vice Chair or Chemical Substance Subcommittee Chair **or**
- Preparation of at least four *Documentation* each year (at least two should be for new substances)

3. TLV® PRODUCTION GUIDE

a) Description of Procedures

The following list shows the process by which a TLV® *Documentation* is developed, from identification of the substance to approval by the Committee.

- Substance/Issue identified for study (through Substance Selection process)
- Steering Committee selects items for action by Committee; Chemical Substance Subcommittee Chairs select items for action; member agrees to prepare *Documentation*
- List of substances/issues under study published annually in TLV® Book to allow public review and to solicit comments and data
- Chemical Substance Subcommittee member gathers information and prepares draft *Documentation*
- *Documentation* reviewed by the Chemical Substance Subcommittee
- Subcommittee decides, by consensus, to bring a *Documentation* to the Committee for its review
- *Documentation* is reviewed by all members of the Committee
- Subcommittee Chair summarizes the *Documentation* and proposes its placement on the Notice of Intended Change (NIC). After a second, the Committee will vote to recommend the TLV® and its *Documentation*. Approval requires a majority of the members present at a full Committee meeting. The Chair does not vote, except in the case of a tie.
- The Committee's recommendation is sent to the Board of Directors
- The *Documentation* is reviewed by all members of the Board.
- If approved by the Board of Directors, the TLV® is listed on the NIC and its *Documentation* is published and disseminated as a "draft"
- A TLV® must be held on the Notice of Intended Change for at least one year prior to approval.
- All comments are reviewed by all Subcommittee members. The *Documentation* is amended if necessary. After Subcommittee review and approval (by consensus), the TLV® and its *Documentation* are brought for review to the Full Committee.
- The *Documentation* is reviewed by all members of the Full Committee
- The Subcommittee Chair will summarize the *Documentation* and propose one of the following actions:
  1) Hold the TLV® on the NIC for an additional year (there must be a good reason for this action),
  2) Change the TLV® and place it for an additional year on the NIC (depending on the degree of change, it may be necessary to hold this TLV® for a second one year period).
  3) Adopt the TLV® and its *Documentation*.
- After a second, the Committee will vote on the proposed action. Approval requires a majority of the members present at a full Committee meeting. The Chair does not vote, except in the case of a tie.

- The Committee's Recommendation is sent to the Board of Directors.
- The *Documentation* is reviewed by the Board
- If approved by the Board of Directors, the TLV® and its *Documentation* are published.

b) TLV® Documentation Format

An outline of a TLV® *Documentation* is included in Appendix C.

The purpose of the TLV® *Documentation* is to clearly describe, present and interpret the appropriate scientific information supporting the derivation of the TLV® and its associated notations for a given chemical. The entire *Documentation* should be no longer than 10 pages in length. It should be kept in mind that a TLV® *Documentation* is not a complete review of all the literature available on a particular substance. It has as its purpose the derivation of a number and the identification of notations, for the purpose of protecting employees in occupational settings. The primary user of the TLV® *Documentation* is the industrial hygiene professional.

4. LITERATURE SEARCH

For new TLVs®, the Committee Member should request a full literature search using the appropriate on-line databases. The request form shown in Appendix D should be used to request this search. Basic toxicology and other references should be consulted (see Appendix E). ACGIH® staff or other Committee members may provide assistance with those references to which a member does not have access.

For TLVs® requiring revision, the Committee member should request an electronic copy of the original TLV® *Documentation* from ACGIH®. Staff should provide copies of any references currently on file. A full literature search should then be conducted (by member or staff) starting with the date of the last reference listed in the TLV® *Documentation*, using on-line databases and references listed in Appendix E.

Primary references should be obtained. Members are encouraged to use local libraries; however, if such access is difficult they may request that ACGIH® staff obtain copies of the references for them. (It should be kept in mind that peer-reviewed, published materials will serve as the backbone of a *Documentation*, particularly for the justification of the TLV®; if non-peer-reviewed materials are necessary, the member should discuss this with the CS Subcommittee Chair. If the references are considered necessary and acceptable, the member should provide a copy of these materials to ACGIH® upon completion of the draft *Documentation*.)

Copies of primary references used in a previous TLV® *Documentation* should also be obtained, particularly if used to justify the TLV® value.

5. COMMITTEE STRUCTURE

a) Organization Chart

The Committee organization chart is shown in Appendix I.

b) Position Descriptions

TLV® Committee Chair

Method of Selection and Appointment. The Chair of the Committee is selected through an internal Committee nomination and vote process, the results of which are sent to the Board for final selection and approval. Six months prior to the expiration of the current Chair's appointment, the Membership Committee will seek nominations from Committee members for candidates. Candidates may be drawn from current members of the Committee or may be people from outside the Committee. The latter must meet the criteria for voting membership within ACGIH®, as well as the membership criteria of the TLV® Chemical Substances Committee. The Membership Committee will screen nominees and present a slate of two or more names to the Committee, accompanied by background information and a statement from each nominee. All Committee members will be asked to vote for one of the nominees. The Membership Committee will tally votes. The slate of nominees and number of votes received by each nominee will be sent to the Board of Directors for final selection and approval.

The Chair of the TLV® Chemical Substance Committee will hold the appointment for three years. This appointment may be renewed for more than one term, following the nomination and selection process described above.

Duties. The Chair leads the TLV® Chemical Substances Committee and works closely with the Vice-Chair and Steering Committee to ensure the Committee's progress toward fulfilling its mission and goals. The Chair:

- Assists and oversees Chemical Substance Subcommittee activities
- Monitors the annual selection of substances (activities undertaken by the Substance Selection Subcommittee)
- Oversees budget management, spending, meeting plans (with assistance from Staff Liaison)
- Monitors overall workload and makeup of the Committee
- Monitors and assists the activities of the Administrative Subcommittees
- Assures regular, clear communications with staff and Board of Directors by interacting with the Board Liaison, Staff Liaison, and other staff or Board members, as necessary
- Assures regular, clear communications with external parties by reviewing all comments received and providing input to replies prepared by Staff Liaison

- Assures communication between all members of the Committee by consulting regularly with the Steering Committee (Chair, Vice-Chair and Chemical Substance Subcommittee Chairs)
- Consults regularly with the Vice-Chair to assure proper functioning of internal Committee activities
- Works closely with the Chairs of the Administrative Subcommittees to assure their groups are functioning according to their guidelines and policies. In particular, the Chair will work directly with the Chairs of the Communications and Notations Subcommittees.
- Represents the TLV®-CS Committee to the outside world
- Represents the TLV®-CS Committee to the ACGIH® Board of Directors and communicates and consults regularly with the Committee's Board Liaison

Reporting. The Chair reports directly to the Board of Directors of ACGIH® and the Committee's Board Liaison.

Assistant to the Chair

Method of Selection and Appointment. The Assistant to the Chair will be selected by the Chair of the Committee after consultation with Staff.

Duties. The Assistant to the Chair will work directly with the Chair in providing support and assistance in assuring that the Chair's responsibilities and various activities are adequately carried out. The job description of this Assistant may vary with the individual in the Chair position and will be defined and negotiated with ACGIH® administration.

Reporting. The Assistant to the Chair will report directly to the Chair. The Chair will report on activities and progress of the Assistant to the Board and staff as requested.

Vice Chair

Method of Selection and Appointment. The Committee Chair recommends the Vice Chair to the Board of Directors, which approves the recommendation and appoints the Vice Chair for a three-year term. The Vice Chair may be re-nominated by the Chair and re-appointed by the Board for more than one term.

Duties. The Vice Chair is responsible for assisting the Chair in assuring that internal Committee functions are adequately cared for. The Vice Chair will undertake the responsibilities of the Chair when s/he is unable or unavailable to do so. The Vice Chair may be a candidate for future appointment as Committee Chair.

The Vice Chair assists the Chair as necessary. In particular, the Vice Chair participates in the Steering Committee and oversees internal Committee activities that support Documentation preparation and membership.

Specifically, the Vice Chair will:

- Assure the internal functioning of the Committee. As such, the Vice Chair is specifically responsible for overseeing the Administrative Subcommittees.
- Determine the make-up of all the Administrative Subcommittees, in consultation with the Chair. Each year, members will be asked for their preferences and assigned to an Administrative Subcommittee. Every effort will be made to meet a member's preference, if possible. However, the Vice Chair will also ensure an appropriate mix of members on the Administrative Subcommittees (by CS Subcommittee affiliation, professional background and skills, etc.).
- Participate in decisions on new members by consulting regularly with the Membership Subcommittee.

Reporting. The Vice Chair will report to the Chair of the Committee on his/her individual activities and the activities and make-up of the Administrative Subcommittees.

Chemical Substance Subcommittee Chairs

Method of Selection and Appointment. The Committee consists of three Chemical Substance (CS) Subcommittees:

- Hydrogen, Oxygen and Carbon Compounds (HOC)
- Dusts and Inorganic Compounds (D&I), and
- Miscellaneous Compounds (MISCO).

Each of these Subcommittees is headed by a Chair, who is nominated by the Committee Chair in consultation with the Vice Chair. There is no established term for a CS Subcommittee Chair. The Chair will review the activities of each CS Subcommittee Chair on a regular basis, seeking input from members of the Subcommittee. While continuity is important in ensuring the on-going productivity of these Subcommittees, it is also important to build leadership skills among all Committee members who demonstrate skills and interest. Subcommittee Chairs are strongly encouraged to identify, in consultation with the Committee Chair, another individual within their Subcommittee to serve as an assistant or co-chair. This person should become versed in the management of the Subcommittee and should be given opportunities to play a leadership role within the Subcommittee. In case of the Subcommittee Chair's absence, this person should be prepared to chair meetings and ensure progress toward completion of the Subcommittee's activities.

Duties. CS Subcommittee Chairs are members of the Steering Subcommittee. (Assistant or co-chairs, as described above, should be included in Steering Subcommittee meetings, as well.) CS Subcommittee Chairs will not be asked to serve on other Administrative Subcommittees. The CS Subcommittees have the most important function within the TLV® Committee. Thus, the Chair of a CS Subcommittee carries the largest degree of responsibility for assuring that the Committee's products are of high quality and fulfill the goals of the Committee. It is very important that the CS Subcommittee Chair communicates and consults regularly with the Chair, the Steering Committee, the Staff Liaison and with members of their Subcommittee.

CS Subcommittee Chairs are responsible for the Documentation preparation activities of their Subcommittee. In this capacity, CS Subcommittee Chairs:

- Assign substances to individual members, within the guidelines of decisions made by the Steering Committee
- Assure that each member meets the expectations for *Documentation* preparation, both in quantity and quality
- Assist members, when necessary, with literature search and retrieval
- Keep members informed of relevant decisions of the Steering Committee
- Track the progress of *Documentation* preparation and keeping members informed of this progress
- Provide feedback to members about their activities with respect to membership expectations.

CS Subcommittee Chairs are responsible for their Committee's productivity, both in quality and quantity of *Documentation*. In this capacity, they will arrange regular Subcommittee meetings throughout the year, establish meeting agendas in consultation with members, and run well-organized and productive meetings. They will also ensure notes are taken for all meetings and will provide copies of these notes to all Subcommittee members and the Committee Chair. Notes may consist of a simple "to do" list, rather than a formal description of the discussion.

Generally, no voting takes place in the CS Subcommittees. Decisions are arrived at by consensus, if possible. However, the CS Subcommittee Chair may ask for a vote of the subcommittee members if consensus is not reached. In this case, a quorum of the subcommittee must be present and a simple majority vote will be required to take a TLV® *Documentation* to the full Committee. The CS Subcommittee Chair must seek subcommittee consensus for all substances currently on the NIC and on the Substances Under Study list. He or she may not bring a TLV® to all members of the Subcommittee without receiving approval from the Committee Chair and the Staff Liaison, at a minimum.

CS Subcommittee Chairs are responsible for ensuring that full communication takes place within the Committee, particularly among the Steering Subcommittee members and with the Staff Liaison. As such they should:

- Review all communications received from external parties and ensure that all members of their Subcommittee have an opportunity to review and discuss all relevant comments.
- Respond to questions from the Staff Liaison in a timely manner.
- Direct all questions and comments (written and oral) received from external parties directly to the Staff Liaison. CS Subcommittee Chairs are expected to refrain from contacting external parties. If such contacts are necessary, they should seek input from the Committee Chair and Staff Liaison prior to initiation. CS Subcommittee Chairs are expected to respond to all external parties by directing them to the Staff Liaison.
- Work with the relevant Administrative Subcommittees on activities not directly related to the preparation of TLV® *Documentation*. For example, internal education events should be planned in consultation with the Communications Subcommittee; external education events should follow the guidelines of the Communications Subcommittee; changes to the TLV® notations, appendices, etc. should be discussed and coordinated with the Notations Subcommittee; and issues related to the selection of new substances should be discussed with the Substance Selection Subcommittee.

Terms. A member may not serve more than three consecutive terms (9 years) as Chair of a Chemical Substance Subcommittee.

Reporting. The CS Subcommittee Chairs report to the TLV® Committee Chair.

Chemical Substance Subcommittee Co-Chairs

Method of Selection and Appointment. Each CS Subcommittee Chair will identify a Co-Chair, in consultation with the Committee Chair.

The Co-Chair will work closely with the CS Subcommittee Chair to assist in leadership and decision-making responsibilities. The Co-Chair may take on the duties of the Chair, in case of the latter's absence. The Co-Chair participates fully in all Committee leadership activities (Steering Committee, etc.).

Reporting. The Co-Chair reports directly to the CS Subcommittee Chair.

Term. A member may not serve more than three consecutive terms (9 years) as Co-Chair of a CS Subcommittee.

Assistants to the Chemical Substance Subcommittee Chairs

Method of Selection and Appointment. The Assistants to the CS Subcommittee Chairs will be selected by the Subcommittee Chairs after consultation with the Staff Liaison.

Assistants will work directly with the CS Subcommittee Chairs in providing support and assistance in assuring that the CS Subcommittee Chair's responsibilities and various activities are adequately carried out. The job description of this Assistant may vary with the individual in the Chair position and will be defined in consultation with the Committee Chair and ACGIH® administration.

Reporting. These Assistants will report directly to the CS Subcommittee Chairs. The Chair will report on activities and progress of their Assistant to staff as necessary.

Administrative Subcommittee Chairs

Method of Selection and Appointment. The Administrative Subcommittee members are responsible for identifying a Chair.

Reporting. The Administrative Subcommittee Chair is responsible for ensuring that the duties of the Subcommittee are adequately fulfilled, as described in the Operations Manual. The Chair is responsible for reporting the Subcommittee's activities to the Chair, Vice Chair and Steering Subcommittee. The Chairs of the Substance Selection and Membership Subcommittees are expected to work most closely with the Vice Chair, who holds primary responsibility for their activities. The Chairs of the Communications and Notations Subcommittees will work most closely with the Chair, who holds primary responsibility for their activities.

c) Description of Administrative Subcommittees

Steering Subcommittee

Method of Selection and Appointment. The Steering Subcommittee consists of the Chair, Vice Chair and the three CS Subcommittee Chairs (HOC, D&I, MISCO). Co- Chairs will participate in the Steering Subcommittee, as well. The Chair of the Committee serves as the leader of this group.

Duties. The Steering Subcommittee:

- Reviews Committee productivity, progress toward goals and mission, spending and budget.
- Sets specific annual goals and recommends an annual Committee workplan to the ACGIH® Board.
- Reviews, changes, and updates Committee policies, with Board approval.
- Is responsible for assuring that Committee resources are properly allocated.
- May identify and use external resources, as necessary.
- Reviews special projects and requests from Subcommittees, as necessary.
- Reviews CS Subcommittee and Administrative Subcommittee.

Membership Subcommittee

Method of Selection and Appointment. The Membership Subcommittee will consist of three or four Committee members who express an interest in participating, selected by the Vice Chair. The Subcommittee will identify a Chair, in consultation with the Vice Chair. Subcommittee appointments are for one year and may be extended for additional years by the Vice Chair. Members of this Subcommittee should represent the range of disciplines on the TLV® Committee.

Duties

New Members. The Membership Subcommittee is responsible for recruiting, reviewing, and recommending new members to the Committee, and for monitoring the probationary progress of applicants considered potential members. Recruitment may be accomplished by a variety of methods, including advertisements and personal communications.

Any person indicating interest in participating on the Committee will be sent an application form by Staff. Applicants will be asked to submit a completed application for membership (Appendix A) and a resume or curriculum vitae. Applicants will be informed of membership expectations and responsibilities of membership on the TLV®-CS Committee (Appendix B) and will be asked to review and accept these responsibilities as part of their application. Staff will review the completeness of applications received and issue a letter confirming receipt of the application. Complete applications will be sent to the Chair of the Membership Subcommittee.

Criteria for individual applicants and their fit within the overall membership of the Committee are described in the Membership section.

Upon receipt of an application, the ACGIH® staff will send copies of the application and resumes to members of the Membership Subcommittee. The Membership Subcommittee will review and consider all new applicants at least once per year or more frequently if necessary.

All TLV®-CS Committee Members will be notified of the names of applicants who are considered potential members and asked to forward their comments to the Membership Subcommittee Chair within two weeks. The Membership Subcommittee will then forward acceptable applications and resumes to the Steering Subcommittee at least once each year.

If the Steering Subcommittee indicates its interest in a candidate, the TLV® Committee Chair will extend an invitation to attend and participate in a full Committee meeting. The applicant will be given the opportunity to attend all three of the CS Subcommittee meetings and a full Committee meeting, as well as meetings of the Administrative Subcommittees (except Membership), if possible.

The Membership Subcommittee will ask the Subcommittee Chairs and Committee members for an assessment of the applicant. If the applicant is acceptable and continues to express an interest in becoming a member, the TLV® Committee Chair will assign the applicant to a CS Subcommittee for a one-year probationary period. Applicants will be referred to as member-candidates during this period. As such, they will be expected to attend all meetings of their CS Subcommittee and of the Committee. The respective CS Subcommittee Chair will identify and assign responsibilities to the member-candidate during the probationary period. These responsibilities will include the assignment of a document to be developed as a draft to the Subcommittee during the probationary year, administrative activities, and other duties. The member-candidate will also be expected to interact productively on at least one Administrative Subcommittee. The member-candidate will not be allowed to vote in full Committee meetings during the probationary year, but will be expected to participate fully in CS Subcommittee and Committee discussions.

The CS Subcommittee Chair will notify the Membership Committee that the applicant has or has not met the requirements for membership. The Membership Subcommittee will then submit the names of all applicants who have completed their probationary period satisfactorily to the TLV® Committee Chair. The Chair will solicit input from all Committee members concerning membership for applicants completing their probationary period. The Committee Chair will evaluate each applicant and make the final decision concerning a recommendation for membership. Names and resumes of recommended applicants will then be forwarded by Committee Chair to the Board for formal appointment.

Should an applicant not fulfill the criteria of membership, a letter will be sent by the Committee Chair thanking the applicant for his/her interest. Should an applicant not be selected for other reasons, a letter will be sent by staff thanking the applicant and asking for the applicant's interest in remaining in the pool of candidates for future consideration.

Nominating the Committee Chair. The Membership Subcommittee will serve as the nominating Committee for the Committee Chair. See the section on Method of Selection and Appointment for the Committee Chair for more details on this process.

Reporting. The Chair of the Membership Subcommittee will be asked to report activities and progress to the Vice-Chair and the Steering Subcommittee on a regular basis.

Communications Subcommittee

Method of Selection and Appointment. The Communications Subcommittee consists of one member from each of the Chemical Substances Subcommittees, nominated by the Vice Chair in consultation with the CS Subcommittee Chairs, and one member from the Education Staff. A liaison from the staff may also participate in this subcommittee's activities, at the request of the subcommittee chair. Activities of the Communications Subcommittee will be largely dependent on the number of proposals submitted. The Subcommittee Chair will prepare an annual report of Subcommittee activities for the Steering Committee. When proposals originate within a specific Chemical Substances Subcommittee, the member from that Subcommittee will take the lead role in communicating between the two Subcommittees and championing that specific proposal through the selection and implementation process.

The Communications Subcommittee consists of one member from each of the Chemical Substances Subcommittees, nominated by the Vice Chair in consultation with the CS Subcommittee Chairs, and one member from the Education Staff. Activities of the Communications Subcommittee will be largely dependent on the number of proposals submitted.

Duties. The mission of the Communications Subcommittee is to foster the educational and outreach efforts activities of the CS-TLV® Committee. The Communications Subcommittee is responsible for reviewing and developing ideas and plans for future symposia (scientific presentations) and workshops (educational forums). For internal educational purposes and activities, this Subcommittee will seek input from all TLV® Committee members and the Staff Liaison when deciding topics. For external educational and outreach activities, the Subcommittee will work closely with the Committee Vice Chair, the Education Staff liaison and other Staff, (as necessary,) when formulating its ideas. External activities require review and approval from the Steering Subcommittee prior to their implementation.

To carry out its mission, the Communications Subcommittee will:

- Assist Subcommittees in identifying and developing ideas for possible workshops, conferences, courses, symposia, meetings, or other outreach events.
- Assess the merit of each external or internal proposal in terms of its value to the Committee, users of the TLVs®, the ACGIH® membership, other professional bodies, and potential for impact on workers.
- Communicate regularly to the Steering Committee, TLV® Committee and ACGIH® regarding the topics that are under consideration for possible future educational/outreach events.
- Provide assistance to the ACGIH® designated staff and Subcommittees in efforts to organize and plan events of value to the CS-TLV® Committee.
- Work with Staff in developing educational tools and programs to assist in educational and outreach efforts.
- Ensure that all TLV® Documents are consistent in format and presentation with the guidelines established in the *Documentation* Template.

The Communications Subcommittee has other roles in support of its mission. To assist TLV® Committee members in identifying target audiences for future educational/outreach events, an inventory of professional organizations that may have members interested in TLVs® will be developed. Planned meetings of these associations and organizations will also be part of the inventory and updated regularly. The Communications Subcommittee highly recommends that Committee members consider the possibility of satellite conferences, or co-sponsoring organizations, in the refinement of their ideas. Costs of undertaking an event may be reduced, and the attendance increased, through appropriate identification of target audiences, locations, and suitable timing. Although the Communications Subcommittee does not consider finances in its evaluation, income and expenses are part of the ACGIH® Partnership Guide TAB P analysis and therefore may influence the likelihood of an event being ultimately approved for development. The Communications Subcommittee will follow the procedure described in the section on Workshops and Symposia for evaluating new proposals.

This Subcommittee will work closely with the CS Subcommittees to assure that all TLV® *Documentation* are consistent in format and presentation. This Subcommittee will also work with other individual Subcommittees members or other subcommittees in developing additional publications (journal or newsletter articles, for example) that will educate users of the committee's process or decisions. The Subcommittee may develop materials for the ACGIH® website or write articles for trade association newsletters. This Subcommittee is expected to work closely with the ACGIH® publications staff, as necessary. The Communications Subcommittee is expected to develop materials for the purposes of informing Committee members about important issues as well as educating users about TLVs®. The Subcommittee will have as its goal education of and information for users; its means of communication will be through written articles in a variety of media (trade association newsletters, letters to the editor, scientific journals, etc.).

To encourage excellence in educational and outreach activities of the TLV® Committee, the Communications Subcommittee will assist the staff in education evaluation. New instruments for evaluation will be developed specifically designed with the mission and goals of the CS-TLV® Committee in mind. Results of these comprehensive Education evaluations will be entered into a database for use in future planning of events.

Reporting. The Communications Subcommittee will report its activities and recommendations to the Vice Chair on a regular basis. An annual report of activities will be provided to the Vice Chair and the Steering Committee.

Notations Subcommittee

Method of Selection and Appointment. The Notations Subcommittee will consist of at least one member from each of the three CS Subcommittees, designated by the Vice Chair. The subcommittee will select its own chair, in consultation with the Vice Chair. The BEI® Committee Liaison will be considered a member of this Committee and will be kept informed of all relevant activities, discussions and meetings. Liaisons from other ACGIH® Committees or task groups (e.g., Physical Agents, Air Sampling Procedures) may also be identified and asked to participate in the Subcommittee's activities, as the need arises.

Duties. The Notations Subcommittee has as its mission to:

- Determine the appropriate notations for TLVs®.

- Facilitate consistent review of all notations.
- Respond to emerging issues as they arise.

Specific responsibilities of the Subcommittee include:
- Review all current notations and recommend changes and modifications as necessary in their definitions.
- Develop criteria that guide authors in determining which notations are appropriate and how they should be applied.
- Develop a list of experts (internal and external to the Committee) that can be used as consultants for specific notations.
- Recommend workshops, seminars, or tutorials for the purpose of providing input to the Committee on emerging issues.
- Establish ad hoc groups, where necessary, to consider special issues.
- Develop "stock" language that can be used in *Documentation* and in the TLV®/BEI® book to describe notations and special issues.
- Ensure that the application of notations is consistent across the three CS Subcommittees.

It is the responsibility of the CS Subcommittees and individual authors to ensure that notations are both considered and applied for specific substances. The Notations Subcommittee will not review every *Documentation*; rather, it will serve as a consultant concerning the applicability of a notation to a specific substance. The *Documentation* author is responsible for the initial decisions about notations.

The Notations Subcommittee will also serve as a clearinghouse of information about individuals who may offer additional assistance to an author about a specific notation. Such consultants may be other members of the Committee or may be individuals external to the Subcommittee. In the case of the latter, they may carry the official designation of "consultant" to the Committee or they may serve in a more informal consulting role.

At this time, the types of notations that should be addressed by an author and on which they might consult with the Notations Subcommittee include:
- Carcinogen
- Skin
- BEI®
- Sensitizer
- Critical effects

Those issues for which the Notations Subcommittee will NOT provide review include:
- Mixtures
- Atypical work schedules
- STEL
- TWA
- Ceiling

In the case of the adoption of a new notation, the Notations Subcommittee will be responsible for developing a written definition and assuring adequate review within the Committee.

The Notations Subcommittee will be responsible for including staff and other ACGIH® Committees in their activities and discussions, as applicable.

Reporting. The Notations Subcommittee will keep the Vice Chair and Steering Subcommittee informed of its activities on a regular basis.

Substance Selection Subcommittee

Method of Selection and Appointment. The Substance Selection Subcommittee will consist of four members of the TLV® Committee, preferably with representation from each of the CS Subcommittees. The subcommittee will select its own Chair, in consultation with the Vice Chair. A member of the staff may also participate on this subcommittee.

Duties. The Substance Selection Subcommittee will develop, on an annual basis, two lists of substances that should receive a high priority for the development of new or revised TLVs®. One of these lists will identify substances that do not have TLVs®, while the other will identify substances that already have TLVs® but which should be reviewed to update their *Documentation* and possibly revise the TLV®. These lists will be transmitted annually to the TLV® Steering Committee, which will identify those substances to be assigned to CS Subcommittees for *Documentation* development.

Reporting. The Substance Selection Subcommittee will keep the Steering Subcommittee informed of its progress on a regular basis.

Substance Selection Process

STAFF ACTIVITIES

OEL DATABASE

On a continuing basis, the staff will maintain a database of Occupational Exposure Limits (OELs) recommended by other organizations. These organizations will include (at a minimum) the following:

- MAK Commission
- UK Health and Safety Executive
- European Union (DG V)
- OSHA
- MSHA
- NIOSH
- AIHA WEELs
- Other national and international organizations, as identified by the Subcommittee or staff

PRODUCTION VOLUME INFORMATION

Also on a continuing basis, the staff will obtain reports of production volumes of chemicals from sources including:

- Chemical and Engineering News
- Organization for Economic Cooperation & Development (OECD)
- Chemical Manufacturers Association
- U.S. Geological Survey
- Trade Associations

To the extent possible, both US and worldwide production volumes should be obtained.

TLVs® REQUIRING UPDATES

The Subcommittee will identify TLV® *Documentation* that have undergone a complete revision more than 10 years ago.

SUBSTANCES WITHOUT TLVS

Every two or three years, the subcommittee will prepare a list of the top substances by production volume from the OECD list of high production volume chemicals, which do not have TLVs®, and which have toxicity profiles prepared pursuant to the "Screening Information Data Sets" (SIDS) program. Additional substances may be drawn from the OECD HPV list. Appended to this list will be those substances from the annual production reports of the U.S. Geological Survey and which also do not have TLVs®. The substances in the combined list will be ranked by production volume.

The list will be circulated to all members of the TLV® Committee with a request that they nominate substances for the development of TLVs® based on their own knowledge of the toxicology and worker exposures for the substances. They will also be asked to nominate additional substances that are not on the list but which they feel should be considered for TLV® development. (These substances would generally be by-products of production processes but which are not articles of commerce.) The staff will collate the substance nominations and prepare a listing of the top substances ranked by number of nominations. This list of the top 40 substances without TLVs® will then be transmitted to the Steering Subcommittee.

ACTIVITIES OF THE SUBSTANCE SELECTION SUBCOMMITTEE

SUBSTANCES WITH TLVs®

Annually, the Substance Selection Subcommittee will review the information collected by the Staff on substances with TLVs® and assign point values to each substance based on the following criteria:

Basis	Number of Points
New relevant toxicology data	1-15
Production volume in the US (metric tons)	
<100	2
100-10,000	4
10,000-1 million	6
1-100 million	8
>100 million	10

Significant non-US production	2-10
Not articles of commerce but significant exposures	2-10
Inconsistencies between the TLVs® of different substances	1-5
Age of most recent primary reference >10 years	1-5
Another OEL differs from the TLV® by a factor of more than two	0 or 5

The Substance Selection Subcommittee will transmit to the TLV® Steering Committee a list of the top substances by point ranking. The criteria used for each point ranking will also be identified in the list.

STEERING COMMITTEE ACTIVITIES

Based on the substance lists provided by the Substance Selection Subcommittee, available resources, expertise of the members of the TLV® Committee, and other criteria, the Steering Committee will identify substances to be assigned to the CS Subcommittees for TLV® *Documentation* development.

6. COMMUNICATIONS

a) External to the Committee

Groups That Set Occupational Exposure Values

The CS-TLV® Committee has undertaken as one of its goals regular communication and interaction with other national and international groups responsible for determining occupational exposure guidelines.

The CS-TLV® Committee and its three CS Subcommittees have established close contact and direct interaction with the German MAK group in an effort to share information and cooperate on decision-making, where possible. The Chair and Staff Liaison will work closely with the Director of the MAK in assuring on-going interactions between the groups. Individual members from the CS-TLV® Committee may be asked to attend MAK meetings or work directly with MAK members. MAK members may be invited to attend both CS Subcommittee and full Committee meetings. The Steering Subcommittee will review this relationship on a regular basis and attempt to ensure its on-going success in sharing scientific information about chemical substances relevant to establishing occupational exposure guidelines.

The CS-TLV® Committee has had a similar on-going relationship with the AIHA WEEL Committee. As such, the WEEL Committee has appointed a liaison to the CS-TLV® Committee, who attends and reports to the CS-TLV® Committee as necessary. The Chair and the Staff Liaison perform similar liaison activities at WEEL Committee meetings.

The Chair and Staff Liaison will also work together to build similar links with other such groups. These activities will be reported to the Steering Subcommittee, the Committee and the Board as they occur.

Groups with Interest in TLVs®

The Committee recognizes that there are many different groups with an interest in the TLV® process and its outcomes. The Committee has an obligation to assure that all such parties are given timely and complete information about its process and decisions. At the same time, it is important that these external parties not compromise the Committee's decision process, which is based solely on peer-reviewed scientific information. Thus, it has established written policies and procedures that allow input from external groups to the Committee concerning substances currently under review. These policies and procedures are described below.

Invitations to Present at Subcommittee or Committee Meetings

The most important decisions of the Committee occur within the Chemical Substance Subcommittees as they prepare, review and revise TLVs® and *Documentation*. It is the responsibility of the CS Subcommittees to assure that they have obtained a thorough overview of the available peer-reviewed literature, in addition to input from recognized

scientific experts (if necessary). The CS Subcommittees may invite experts who are not part of the Committee to provide written input or review of a *Documentation*; they may also invite such experts to attend a Subcommittee meeting. Such invitations may be initiated and extended by the CS Subcommittee Chair, after consultation with and approval from the Committee Chair. The guidelines used to assess whether a group or individual receives an invitation are outlined below.

An external group may express an interest in making a presentation to the CS-TLV® Committee about a specific substance or issue. This group will be asked to provide written materials which demonstrate that they have something significant to add to the Committee's review of a substance and which describe, in detail, the content of their presentation. These materials must be received at least 1 month prior to a scheduled CS Subcommittee or full Committee meeting. These materials must be sent to the Staff Liaison (with an appropriate number of copies) and will be distributed to all members identified by the Staff Liaison and the Committee Chair. Following review by the Chair with input from other members and the Staff Liaison, an invitation *may* be extended to the group to make a presentation at a Subcommittee or full Committee meeting. Generally, however, such an invitation is unlikely unless the group has demonstrated that the information they are providing is significantly new and different from that currently available and that such information has received appropriate scientific peer review.

External parties are encouraged to send their comments and input to the Committee in writing. The Chair and the appropriate CS Subcommittee will review all written comments and make adjustments to the documentation if necessary. The Chair and Staff Liaison will consult on the appropriate response, which will be prepared only by the Staff Liaison. All such correspondence must be initiated and followed up by the Staff Liaison only. No external correspondence (written or oral) should be undertaken by any member of the Committee (including the leadership). Exceptions may be made, but only after thorough consultation with the Staff Liaison and Committee Chair.

Confidentiality

The CS-TLV® Committee is under no obligation to inform any particular group about its activities or decisions. The Committee attempts to communicate with its users and interested parties by publishing its decisions, following a clearly delineated process. Authorship of *Documentation* is a confidential matter and generally not known by members external to the CS Subcommittee. Such authorship, if known, may not be discussed within the Committee or revealed to any person external to the Committee (including consultants). Individual members are encouraged to carefully guard information about their own activities. Methods for seeking information from external parties while ensuring anonymity should be discussed with the Subcommittee Chair or Committee Chair. Every member must assure the anonymity of all other members of the Committee, both within and external to the Committee (including the ACGIH® organization and its other Committees and Board of Directors). Information, materials, Documentations, etc. may not be shared with anyone external to the Committee without first seeking approval from the Committee Chair.

b) Internal Communications

Communications Within Committee

The CS-TLV® Committee relies on meeting minutes for documenting its activities and tracking its progress.

Formal minutes will be taken at all full Committee meetings, generally by the staff liaison or Assistant to the Chair. These minutes are used to document the activities and formal votes of the full Committee (without identification of individual names). Copies will be sent to all members of the Committee, other invited guests and attendees, and the Board Liaison.

Formal minutes are not required at Subcommittee meetings. However, all Subcommittees should keep a record of their meetings. At a minimum, Subcommittee notes should indicate the date, members present and absent, important points of discussion, major decisions taken, and future activities planned. Copies of these notes should be sent to the Committee Chair (or the Assistant to the Chair) after each meeting.

Communications Between the Committee and ACGIH® Staff and Board of Directors

The Committee assures timely and consistent communication with the ACGIH® organization through its Board and Staff Liaisons. The Staff Liaison attends all full Committee meetings and many of the CS and Administrative Subcommittee meetings. The Staff Liaison communicates regularly with the Committee Chair about all Committee activities. The Staff Liaison works closely with the Committee Chair on all issues, including budgeting and spending, meeting arrangements, publications, harmonization, communications with external parties, etc.

The Board Liaison also attends full Committee meetings, providing input to the Committee from the Board of Directors and relaying Committee concerns and thoughts to the Board. The Board Liaison also works with the Chair during budgeting, policy-making and other issues that bear directly on the organization.

7. SYMPOSIA AND WORKSHOPS

a) Procedure for Developing a Symposium or Workshop

The education of TLV® committee members is an important aspect of the development of TLVs® and TLV® *Documentation*. Suggestions for educational symposium topics should be forwarded to the Education Staff of ACGIH® or the Chair of the Communications Subcommittee, in writing. Symposium topics can come from Committee members, ACGIH® Staff, and external parties. The proposal should include a justification for the necessity of the symposium, the topic's relevance to the CS-TLV® Committee, a suggested list of participants, and if possible, a list of potential academic, governmental, or industrial sponsors.

Several criteria will be used by the Communications Subcommittee to determine the appropriateness of the symposium as being of interest to the TLV® Committee. A symposium must be the most efficient format in which to present TLV® committee members with new information that will assist in the scientific judgment used in the setting of TLVs® and in the writing of supporting *Documentation*.

Because of the timing of TLV® setting and *Documentation*, it is important that a symposium be suggested as early in the process as possible. Symposia require considerable time, commitment, and manpower to develop and, thus, proposals should preferably be submitted while a substance is on the "Under Study" list. Symposium suggestions submitted while a substance is on the NIC will be considered, but usually this will be too late in the decision-setting process. A symposium will not be favorably reviewed if its purpose is solely to provide a forum for voicing opinions about existing data. Rather, there must be on-going research, scientific uncertainty about currently available data, or another scientific reason for the symposium. The Communications Subcommittee will focus its review on how well a symposium adds to the scientific understanding and decision-making of the CS-TLV® Committee.

Representatives of external organizations may have expressed a desire to meet with the CS-TLV® Committee because the Committee might benefit from discussions of the scientific data or because the many issues to be discussed on a given chemical are likely to be important and of interest to a wide range of interested parties. Yet symposia require commitment of substantial resources and presentations and discussions are often scheduled for a period as long as two days, far more time than the CS-TLV® Committee could commit to a single topic. Thus, it is important that care be taken in the review and selection of topics for symposia.

The Communications Subcommittee will review the proposal (see Appendix H for Symposium Proposal Form) in a timely fashion and rate its relevance to the ongoing TLV® process. The Communications Subcommittee may seek additional input from members of the TLV® Committee or other experts, as necessary, during its review. The Communications Subcommittee will make a written recommendation to the Steering Subcommittee, with a brief description of its review process and the reasons for its recommendation. The Communications Subcommittee will communicate its recommendation to the individual(s) who proposed the symposium topic, as well. The timetable for proposing and approving symposia is included in Appendix G.

The Steering Subcommittee will review the original proposal and the recommendation of the Communications Subcommittee. It may choose to seek further input from individual groups or members of the Committee in its review. The Steering Subcommittee will make a final recommendation to the Education Director, indicating whether the TLV® Committee has an interest in and wishes to participate in the development of a particular symposium. It will communicate its recommendation to the individual(s) who proposed the symposium topic, as well.

If a symposium proposal recommended by the TLV® Committee is accepted by the Education Director, the Steering Subcommittee will identify a small "task force" to work with ACGIH® Staff during the development phase. It is recommended that a member of the Communications Subcommittee be appointed to participate on this task force. It is also recommended that a member of the Steering Subcommittee serve as a member. The Steering Subcommittee will identify one member of the task force responsible for reporting its activities to the Steering Subcommittee on a regular basis. The task force will work closely with the Education Director and, in addition to regular reporting to the Steering Subcommittee, will seek input and ideas from TLV® Committee members about sponsors, speakers, format, etc. The task force will be responsible for ensuring that the TLV® Committee's scientific decision-making needs are met and that all relevant external parties have an opportunity to give input to the planning of a symposium.

If a symposium proposal is rejected, the Education Director will be informed of the proposal and the Steering Subcommittee's review. The individual who submitted the proposal will also be notified. The Director may decide to proceed without the TLV® Committee's formal sponsorship or involvement. In this latter case, potential symposium sponsors and attendees must be made aware that the TLV® Committee has expressed no interest in formal sponsorship or participation. In addition, it must be made clear that TLV® committee members will not attend the meeting in their capacity as members or representatives of the TLV® Committee, although they may, of course, attend as interested scientists.

8. APPENDICES

a) Membership Application

Thank you for your inquiry into membership in this Committee. To assist the ACGIH® TLV®-CS Membership and Executive Committees in its review and selection of new candidates for the TLV®-CS Committee please complete the following information and submit resume/curriculum vitae.

1. How would you describe your profession? Use ++ for major and + for minor, if applicable.

__ Industrial Hygienist
__ Epidemiologist
__ Occupational Physician
__ Toxicologist
__ Other, please specify _____

2. Do you have area(s) of specialization (e.g., carcinogenicity, risk assessment)? List up to three areas in which you consider yourself specialized or could provide expertise to the TLV® Committee.

3. How many years have you spent in your major profession?
   a. < 5 years
   b. 5 to 10 years
   c. 11 to 20 years
   d. >20 years

4. What professional certification(s) do you hold? Circle all that are applicable.
   a. CIH
   b. CSP
   c. DABT
   d. PE
   e. ROH
   f. Medical Boards, specify _____
   g. Other, please specify _____

5. What degree(s) do you hold?
   a. BA/BS
   b. MA/MS/MPH
   c. DrPH/PhD/ScD
   d. DVM/VMD
   e. MD
   f. Other, please specify _____

6. Have you any previous writing experience? Have you any previous public speaking experience? If so, please describe.

7. How many years' experience do you have serving on Committees?

a. <3 years
b. 3 to 5 years
c. 6 to 9 years
d. >9 years

8. On which TLV®-CS Subcommittee are you interested in serving? Which Subcommittee would you best fit?

a. Hydrogen, Oxygen and Carbon (HOC): Chemicals only containing hydrogen, oxygen and carbon such as benzene, toluene and naphthalene
b. Dust and Inorganics (D&I): Substances such as metals, silica and coal dust
c. Miscellaneous Chemicals (MISCO): All other substances such as mercaptans, halogenated substances and organo-phosphates

9. What are your primary reasons for wanting to join this Committee?

10. Have you reviewed the membership expectations of this Committee? Do you have adequate time to devote to this Committee?

11. Please attach a current CV.

b) Membership Expectations and Responsibilities

Expectations and Responsibilities of Members of the Threshold Limit Value – Chemical Substances Committee

Appointments to the TLV®-CS Committee will normally be for terms of three years, with an annual review by the respective Subcommittee Chair – reappointment to successive three-year terms is possible

Each Member is expected to complete two or more TLV® *Documentation* per year (with at least one being a substance for which no TLV® currently exists) and is expected to peer review TLVs® developed by other Members

Members will be assigned to one of the three chemical substances Subcommittees, and will be expected to contribute to administrative functions of the Committee

Members are expected to attend four (4) meetings annually of the TLV®-CS Committee and Subcommittees; the duration of these meetings is 2-3 days

Members must comply with the confidentiality requirements of the Committee, and be willing to disclose conflicts of interest and other sources of possible bias

Members are expected to interact in a collegial and professional manner

Members with more than three years tenure on the TLV® Committee are expected to mentor and otherwise assist more recently appointed Members

c) TLV® Documentation Shell

General Instructions for Preparing Main Body of the TLV®-TWA *Documentation*

The primary purpose of the TLV® *Documentation* is to describe and analyze the scientific literature that specifically supports the derivation of a TLV® and any associated notations. Although the *Documentation* is not intended to be a comprehensive review of the literature for a substance, it should describe the key literature studies that define the range of exposure information and animal and human health effects associated with a substance. To facilitate an organized description of this literature, the TLV® *Documentation* template is divided into appropriate sections for description and analysis of the relevant studies. The review of the literature should not be just a recitation of the findings and conclusions of individual reports, but also must provide appropriate integrated analyses as to which study(s) are most appropriate for consideration (i.e., weight-of-evidence analysis) in derivations of the TLV®. When a study seems to suggest the TLV® or any of its notations should be different from that selected, the reason for discounting this study should be provided.

Bibliographic references in the body of the *Documentation* should be presented as follows:

…text (Smith et.al, 1999; Smith and Jones, 1999; Smith, 1999)

If no studies are available for a major heading (e.g., Animal Studies, Human Studies, etc.) indicate this with the standard statement "No studies available"; if no data are available for a subheading (e.g., Oral, Dermal, Chronic, etc.), do not include the subheading in the outline. Any comprehensive literature reviews relevant to a major heading should be discussed first, before any subheadings. Information in reviews relevant to subheading topics should be summarized there.

For each major heading and subheading, it is not necessary to describe all studies, but only those regarded as reliable and relevant to the TLV® recommendation (adequate description of methodology, reported in peer-reviewed literature, evidence or reproducibility, unpublished GLP report, etc.). Use of unpublished information requires that the entire study or communication be on file at ACGIH® headquarters, and be available for public release if requested.

The text of each section should present the studies regarded as most relevant and reliable to derivation of the TLV® first, followed by descriptions of studies deemed of lesser, but corroborative value. For studies that describe differential or contradictory findings, a brief rationale should be presented for weighting the information of greatest value to the TLV® evaluation (e.g., appropriateness of route of exposure; full characterization of dose-response; adequacy of elements of study design; adequacy of description of study methodologies and results; etc.).

Explanatory note: This template is constructed such that section headings of the actual *Documentation* are described in Arial 12 point Font, the font used by ACGIH® to construct TLV® *Documentation*. The associated instructions for completion of the section are described in Times New Roman Font (font used for this sentence). Make tables of data where possible using the table-making feature of WordPerfect or Microsoft Word.

TLV® *Documentation* Outline

METHYL FUZZELENE. Provide formal chemical name in all capitals

XXX-XX-XX. Provide CAS number(s) describing the substance

FUZZELENE; FUZZSTUFF; ETC. Provide listing of other chemical synonyms(s) attributed to substance

$C_8H_{16}O_2$. Provide chemical equation (provided by staff)

Provide Chemical Structure on separate line from the Chemical Equation (required only if appropriate)

TLV®-TWA, XX units. List current TLV®-TWA expressed in appropriate units; if particulate describe appropriate form

TLV®-STEL, XX units. List current value in appropriate units; if no value assigned, do not list

TLV®-C, XX units. List current value in appropriate units; if no value assigned, do not list

Skin. If no "Skin" notation assigned, do not list

Sensitizer. If no "Sensitizer" notation assigned, do not list

A3, Confirmed Animal Carcinogen. List notation as A1, A2, A3, A4, or A5 with corresponding descriptor, e.g., "Confirmed Animal Carcinogen"; if no notation assigned, do not list

BEI® Notation (If no "BEI", do not list)

Summary

The objectives of the SUMMARY are to concisely

1) describe the critical health effects (animals and humans) providing the basis for the TLV® number and any relevant exposure and/or mechanism information
2) provide a brief summary of the rationale for the TLV®-TWA and any associated notations
3) Staff will automatically insert boilerplate language when particular TLV® forms are not recommended or certain notations were not assigned (see TLV® Recommendation).

The summary may repeat all or portions of the TLV® Recommendation section, although the summary should be limited to less than 250 words. The Summary can contain more than just the TLV® Recommendation, and may touch on other critical effects that do not necessarily drive TLV®.

Chemical & Physical Properties

This section should provide a brief text description of the chemical and physical forms of the substance (e.g., solid, liquid, color, composition, contaminants, decomposition products, etc.). The text should also describe known odor or taste properties (e.g., what is odor/taste? odor/taste threshold?). The text section is followed by a specific listing of properties, some examples of which are provided below. If some of the specific data are not available, do not list the subheading.

Molecular weight: XXX.XX

Specific gravity: X.XXX at XX°C

Melting point: (Centigrade)

Boiling point: (Centigrade)

Vapor pressure: Use torr and specify temperature (Centigrade)

Flash point: (Centigrade)

Flammable limits: lower and upper

Autoignition temperature: (Centigrade)

Solubility:

Conversion factors at 25°C and 760 torr: X ppm = XX.X mg/m^3, 1 mg/m^3 = X ppm

• Major Sources of Exposure

This section should describe the following information, when available, in text format:

1) How the substance is produced (e.g., methods of manufacture, by-product of…).
2) Uses
3) Production volumes and estimated numbers of workers exposures (from Chemical Selection Subcommittee).
4) Major routes of exposure associated with manufacture and use (what forms are encountered during use, e.g., vapor, dusts, aerosol, liquid, etc.). Particle size issues and characterizations, if relevant.
5) Occupational exposure survey study(s), including information such as: job descriptions; monitored exposure levels (TLV®-TWA, range of exposures, etc.); type of sampling (personal, area, duration, grab sampling, etc.); single vs. multiple surveys (optional).
6) Historical exposure evaluation (optional).

Animal Studies

The major section and subsections should describe the relevant *in vivo* and *in vitro* studies supporting assessment and derivation of the TLV®-TWA.

Detailed descriptions of animal toxicology studies are generally not required. However, if known, the minimum information that should be reported for each study described in the subsection below is as follows:

1) Species; sex; route and mode of administration (inhalation, oral gavage, oral diet, dermal, etc.); duration of dosing; specific doses tested; relevant toxic effects; No-Observed-Effect Levels (NOELs), Lowest-Observed-Effect Levels (LOELs), and toxic responses at higher dose levels.
2) Mechanistic studies (e.g., animal model and pharmacokinetic relevance) that provide perspective for appropriate extrapolation of animal findings to humans.
3) Published expert reviews (IARC, WHO, U.S. EPA, U.S. NIOSH, etc.) that offer analysis of human relevance of animal studies.
4) Structure-Activity Relationships (cross-reference to other TLVs – can create common tables to illustrate relationships).

Acute/Subacute (all studies less than 2 weeks duration)

Oral

- As available, incorporate minimum information noted above.
- Describe LD_{50} value(s) or equivalent indicator(s) of toxicity.
- Describe minimum lethal doses (LD_{Lo}, LC_{50}) and any reported clinical signs.
- If no lethality found, indicate full range of doses, clinical observations, and NOEL and effect-level doses.

Dermal

Same as oral above. Include description of nature of applied substance (neat, concentration of solutions and vehicles, formulations, etc.)

- Describe systemic toxicity resulting from skin absorption.
- Describe specific toxicity to skin (irritation, burns, etc.); include assessment (classification) of toxic response (non-irritant, type of irritant — corrosive).

Inhalation

Same as oral above (LC_{50} values). If relevant, include particle size characterization or lack thereof.

Sensitization

Include species, doses, routes of administration, protocol used, ancillary information (adjuvants used, etc.), end results (dose-response; NOEL, ancillary skin irritation, etc.) and classification (skin and/or respiratory sensitizer).

Other studies

- As available, include minimum information noted above for each of the relevant "other studies" described; examples of potentially relevant "other studies" include:
  - Eye irritation.
  - Respiratory irritation RD_{50} studies.
  - etc.

Subchronic (> 2 weeks ≤ 3 months)

- Same information as above, organized by route of exposure.

Chronic/Carcinogenicity (> 3 months ≤ animal lifetime)

- Same information as above, organized by route of exposure.
- Include any carcinogenicity classification determinations published by internationally recognized review bodies (IARC, U.S. NTP, U.S. EPA, MAK, etc.).

Genotoxicity

- Organize by *in vitro* and *in vivo.*
- Describe test systems (bacterial, mammalian cell, etc), final study conclusions (positive/negative; with/without activation. Test systems should not be described in detail.
- If possible, an integrated assessment of the combined genotoxicity findings should be described. These include such observations as: 1) positive findings noted only *in vitro* studies with negative findings in *in vivo* studies; 2) potency of response relative to study positive control agents; 3) dose/concentration responses; 4) etc.

Reproductive/Developmental Toxicity

- Present reproductive studies first, followed by developmental toxicity studies.
- Same information as above, organized by route of exposure.

Absorption, distribution, metabolism and excretion

- Describe animal studies first, followed by human studies.
- If available, key information to be described may include: amount absorbed (percent of applied dose); metabolites formed; estimated half-lives and clearance routes (urine, exhaled air, feces); dose–response evaluations and overall relevance to developing a TLV®.

Human Studies

If there are many human studies with similar designs in multiple populations, make tables of data where possible to summarize the key information listed below. In general, little detail is warranted concerning case reports, with the exception of sensitization. Studies among occupationally exposed populations should be given priority for detailed description.

For key studies, include the following information:

- Type of study (e.g., cross sectional, case control, cohort, experimental, or other);
- Description of study population (include location of study, number of participants, and pertinent demographic information);
- Measurements of disease or death (e.g., death certificates, physical examination, laboratory analyses, questionnaires, etc);
- Measurements of exposure (e.g., laboratory analyses, air measurements, etc);
- Measurements of health effect using tools such as odds ratio, relative risk, standardized mortality/morbidity ratio [SMR], proportional mortality/morbidity ratio [PMR], etc. (e.g., cross shift change in physiologic measurement). Include confidence intervals or p values and whether data were adjusted for other causes of effect and disease;
- Other potential causes of effect and disease (e.g., age, smoking, ethanol, socio-economic class, gender, location), and other exposures present.

Other considerations to be used in evaluating human studies:

- Hill's criteria of causation (e.g., exposure prior to disease, dose response, biological plausibility, strength of effect, consistency of findings with other studies, etc).

Recommended Order:

- Case reports and case studies; disease clusters;
  - Occupational only
  - Accident reports
  - Summarize observed toxicity; include doses or exposure estimates
    - Hierarchy of reports to be described:
      - exposure information is available,
      - chemical information is specific (no other chemicals present),
      - adverse effect(s) potentially attributable to chemical exposure (e.g., irritation, sensitization, CNS responses, etc.)
- Experimental (e.g., chamber studies, cross over)
  - Controlled experiments (all exposure routes)
  - Do not include PK (see above)
  - *In vitro* studies
- Epidemiology
  - General
    - Occupational studies are of primary importance (include general population studies only if relevant to TLV® derivation)
    - Describe:
      - type of study (case-control; cohort, etc.)
      - key endpoints reported
      - dose–response characterization
  - Types of Epidemiology Studies
    - Cross sectional and related (e.g. Panel studies, cytotoxicity studies in humans);
    - Case Control;
    - Cohort (e.g., retrospective, prospective, SMR);
    - Other (e.g., PMR, ecological, meta-analysis and pooled).

TLV® Recommendation

Focus only on study(s) providing the rationale for deriving the TLV® recommendation. For example:

- human study(s)
- animal study(s) expressing most relevant route of exposure, doses, and appropriate responses

Include the relevant bibliographic references (e.g., Smith, 1999). The results of these studies should not be repeated in detail; provide only the key conclusion(s) as they support the rationale for the TLV® recommendation.

Selecting an appropriate TLV®:

1. Decide critical health effects:
    a. Those that occur at the lowest exposure levels and will drive the TLV® number
2. Decide which kind of TLV® (TWA, STEL, C)
    a. Review of the definitions should help elucidate the appropriate form of a TLV®.
    b. Although the type of available data may affect this, in general:
        i. Chronic effects ➔ TWA
        ii. Acute effects ➔ STEL
            1. In some cases, STEL may be selected when it is thought that short, high-level exposures lead to chronic effects.
        iii. Severe, acute effects ➔ Ceiling
    c. Some substances may fit into more than one category.
    d. In exceptional cases, other schemes may be chosen, if clearly described and supported in the *Documentation*.
3. Decide the value of the TLVs®
    a. It may be useful to pull together a table of key studies and findings as they relate to the TLV®. From this information, select a point at which it appears no health effects are likely to occur in workers.
    b. Describe the relationship of recommended TLV® to known human or animal toxicity responses (e.g., Margins of Exposure).
    c. Describe how the TLV® reflects uncertainties in the available data. If the uncertainty in the available data is high, so state. Using professional judgment, adjust the TLV® to reflect an appropriate degree of conservatism.
        i. Uncertainty considerations include:
            When animal data are the primary source
            The quality of the studies
            Available exposure information
        ii. Use language that avoids referring to these adjustments as “factors.”
        iii. The TLV® number should have only one significant figure, unless your data are <u>very</u> precise.
    d. This section should have a clear explanation about each of the items described below. That is, a description of the key health effects, a discussion of why particle size fraction was selected for the TLV® (for aerosols), and the reasoning for the selection of a number. Adjustments do not need to be quantified, but rather explained. Notations and other relevant information should also be described and explained.
4. Consider whether the substance may occur or be generated in the form of an aerosol.

a. If so, it may be necessary to develop a TLV® for one aerosol form in addition to the vapor form.
    i. It may be necessary to determine separate TLVs® for these two forms.
    ii. If the TLV® number is the same for both forms, then a designation of both vapor and aerosol must be made.
b. If the TLV® may refer to an aerosol, one of the three PSS-TLV® designations must be selected. In general, the following relationship will determine which one:

In which part of the respiratory system can deposition or absorption lead to health effects?

	PSS
Throughout respiratory system	Inhalable
Lung airways and gas exchange	Thoracic
Gas exchange areas	Respirable

c. Exposure data that include particle size distributions may be useful in helping identify the PSS.

5. Identify appropriate notations and explain reasoning for their selection
    a. Carcinogenicity designation (see Appendix A in the *TLV®/BEI® Book*)
    b. SEN (see future Appendix in *TLV®/BEI® Book*)
    c. Skin (see future Appendix in *TLV®/BEI® Book*)
6. Staff will automatically insert the following boilerplate language when particular TLV® forms are not recommended or certain notations were not assigned:
    a. Sufficient data were not available to recommend a ***TLV®–STEL***. The reader is expected to be familiar with the section on *Excursion Limits* in the "Introduction to the Chemical Substance TLVs®" of the current edition of the *Documentation of the TLVs® and BEIs®* for the guidance and control of excursions above the TLV®-TWA, even when the 8-hour TWA is within the recommended limit.
    b. A TLV®-**Ceiling** of ____is recommended to minimize the *acute irritation* associated with occupational exposure to _____.
    c. Sufficient data were not available to recommend a ***Skin*** notation.
    d. Sufficient data were not available to recommend a ***SEN*** notation.
    e. Available data on sensitization from exposure to _____ warrants the addition of the **SEN** (sensitization) notation. (cite specific data….)
    f. Sufficient data were not available to recommend a ***carcinogenicity*** notation.
    g. ACGIH® selected an **A2**, Suspected Human Carcinogen, designation because - _____ has been demonstrated to be carcinogenic to experimental animals by mechanisms considered relevant to worker exposures and because there is sufficient epidemiological evidence indicating that it is a suspected human carcinogen.
    h. Therefore, to protect against all effects including cancer, a TLV®-TWA of _____ with an **A3**, Confirmed Animal Carcinogen with Unknown Relevance to Humans, designation is assigned for is assigned for_____.
    i. On the basis of this evidence, the TLV® Committee is proposing a carcinogen classification of **A4**, Not Classifiable as a Human Carcinogen, for _____. An A4

category is appropriate on the basis that no epidemiological cancer studies have been conducted in connection with exposure to _____.

j. XXXXX is a substance for which ***Biological Exposure Indices*** (BEIs®) have been recommended (see BEI® *Documentation* for XXXXX).
k. The TLV® Committee welcomes the **submission of additional information** concerning the toxicity of this compound.
l. A TLV®-TWA of __ mg/m^3, measured as **inhalable particulate**, is recommended for occupational exposure to _____. This recommendation will minimize the particle clearance alterations that have been demonstrated to occur in both animals and human subjects after exposure to _____.
m. One of the characteristics of _____is _____, which are apparently caused by the deposition of particles containing _____ on the alveolar walls. Accordingly, it would be appropriate to state the TLV® in terms of **respirable particulate**. Respirable particulate in a dust cloud is only a small fraction of the airborne material and the numerical value of the fraction depends on the process which generated the dust.
n. The TLV® ***Documentation*** **has been updated** and revised to reflect new scientific data, but the TLV® recommendation has not been changed.
o. Language for "delete", e.g., STEL

TLV® Basis – Critical Effects

This section should briefly list the critical health effects that support derivation of the TLV®. This description will be used to complete the "TLV® Basis – Critical Effect(s)" column in the ACGIH® *TLV®/BEI® Book*. Example descriptors include: Cancer; Irritation; Lung; Neurotoxicity; CNS; Reproductive; etc.

List of Health Effects

Biological System	Descriptors
Circulatory System	Bleeding Anemia Blood Hemolysis Cyanosis
Nervous System	CNS (Depression; Stimulation) Cholinergic Narcosis Neurotoxic Ototoxic Ocular
Respiratory System	Asphyxiation Asthma Bronchitis Fibrosis Irritation Lung (expand)

	Mucostasis Nasal Pneumoconiosis Sensitizer
Dermal	Burns (chemical) Chloracne Corrosion Depigmentation Dermatitis Irritation Sensitizer Uticaria
Reproductive	Reproductive *Expand to define developmental, organs, and gametes*
Hepatic	
Renal	
Musculoskeletal	Bones
Gastrointestinal	
Other	Anoxia Cancer (organ) Metabolic disorder Metal fume fever

TLV® History

The purpose of this section is to describe only the historical and/or pending/actionable activities (dates) associated with the TLV® *Documentation*. It is not intended to describe the detailed history of actions completed on the *Documentation*. See example below:

19XX: TLV®-TWA, XX ppm; proposed
19XX-present: TLV®-TWA, XX ppm
20XX: Documentation revised. Describes current *Documentation* revision efforts; use only when Documentation is revised but TLV® is not changed
20XX: *Proposed:* TLV®-TWA, XX ppm, notation(s). If necessary, describe published (NIC) *Proposed* TLV® values and associated notations that have not been adopted by ACGIH®.

20XX: *Proposed:* TLV®-TWA, XX ppm, notation(s). Describe *Proposed* TLV® recommendation and associated notations under active review and consideration by ACGIH®

References

List in alphabetical order.

Unlike the reference style of the past, use a modified MedLine style, e.g., all extraneous punctuation and capitalization are eliminated in journal citations (e.g., article titles are treated as a sentence).

Journal Articles

List all authors when there are four or less. If five or more, list the first three, followed by "et al.:"

Davies CN: Dust sampling and lung disease. Br. J. Ind. Med. 9:120 (1952).

Deskin R; Bursain SJ; Edens FW: The effect of chronic manganese administration on some neurochemical and physiological variables in neonatal rates. Gen Pharmacol 12:279–280 (1981).

Wagner WD; Fraser DA; Wright PG; et al.: Experimental Evaluation of the Threshold Limit of Cristobalite — Calcined Diatomaceous Earth. Am Ind Hyg Assoc J 29:211–221 (1968).

Online Citations

U.S. National Library of Medicine: Substance name. In: Hazardous Substances Data Bank. Toxicology Data Network (TOXNET). Online at: http://toxnet.nlm.nih.gov/

U.S. Environmental Protection Agency: Integrated Risk Information System (IRIS) Substance File: Substance name. U.S. EPA, Washington, DC (1996). Online at: http://www.epa.gov/iris/subst/0373.htm

U.S. National Toxicology Program: Substance name. In: Testing Information and Study Results, Results and Status. Online at: http://ntp-server.niehs.nih.gov/main_pages/NTP_ALL_STDY_PG.html

Federal Agency Publications

U.S. National Toxicology Program: Toxicology and Carcinogenesis Studies of Manganese (II) Sulfate Monohydrate (cas No. 10034-96-5) in F344/N Rats and B6C3F1 Mice (Feed Studies) Technical Report No. 428. DHHS (NIH) Pub. No. 94-3159. NTP, Research Triangle Park, NC (1993).

U.S. Agency for Toxic Substances and Disease Registry, Toxicological Profile for Manganese (Update). U.S. Department of Health and Human Services, ATSDR, Atlanta, GA (September 2000).

With Author(s)

Anderson HA; Dally KA; Hanrahan LP; et al.: The Epidemiology of Mobile Home Formaldehyde Vapor Concentration and Residents' Health Status. Pub. No. EPA-905/1-83-001. U.S. Environmental Protection Agency, Washington, DC (1983).

Books

Sections/Chapters with Specific Author(s)

Beliles RP: The metals. In: Patty's Industrial Hygiene and Toxicology, 4th ed., Vol. 2C, Toxicology, pp. 2106–124. G.D. Clayton and F.E. Clayton, Eds. John Wiley & Sons, New York (1994).

Matanoski GM: Risk of cancer associated with occupational exposure in radiologists and other radiation workers. In: Cancer Achievements, Challenges, and Prospectives for the 1980s, Vol. 1, pp. 241–254. J.H. Burchenal, Ed. Grune and Stratton, New York (1981).

With Editor(s) Only

Hathaway GJ; Proctor NH; Hughes JP (Eds.): Substance name. In: Proctor and Hughes' Chemical Hazards of the Workplace, 4th ed. Van Nostrand Reinold, New York (1996).

Lide DR; Frederikse HPR (Eds.): Substance name. In: Handbook of Chemistry and Physics, 77th ed. CRC Press, Boca Raton, FL (1996).

Proceedings

Andersen I: Formaldehyde in the indoor environment — health implications and the setting of standards; and discussion. In: Indoor Climate: Effects on Human Comfort, Performance and Health in Residential, Commercial, and Light Industry Buildings, pp. 65–87. PO Fanger and O Volbjorn, Eds. Proceedings of the First International Indoor Climate Symposium, Copenhagen, August 30–September 1, 1978. Danish Building Research Institute, Copenhagen (1979).

Failing A; Knecht U; Woitowitz HJ: Biological monitoring of a standardized tetrahydrofuran exposure (in German). In: Proceedings of the 34th Meeting of the German Society of Occupational and Environmental Medicine in Wiesbaden, pp. 375-376. R Kessel, Ed. Gentner Verlag, Stuttgart (1994).

Boyle MJ: Tropic of Capricorn — assessing hot process conditions in northern Australia. In: Proceedings of 14th Annual Conference, pp. 54–57. Australian Institute of Occupational Hygienists, Adelaide (1995).

Budd GM: Stress, strain and productivity in Australian wildfire suppression crews. In: Proceedings of the Society of American Foresters National Convention, San Francisco, pp. 119–123. SAF, Bethesda, MD (1991).

Industrial Health Foundation: Proceedings of a Symposium on an Industry Approach to Chemical Risk Assessment: Caprolactam and Related Compounds as a Case Study. IHF, Arlington, VA (1984).

CD-ROMs

U.S. National Institute for Occupational Safety and Health: Criteria for a Recommended Standard: Occupational Exposure to Substance name. DHEW (NIOSH) Pub. No. Fill in the number from original reference; 19??. In: NIOSH Criteria Documents Plus CD-ROM.

DHHS (NIOSH) Pub. No. 97-106; NTIS Pub. No. PB-502-082. National Technical Information Service, Springfield, VA (1997).

Merck & Co., Inc.: Substance name. In: The Merck Index, 12th edition on CD-ROM, Version 12:1. S Budavari, M O'Neil, A Smith, et al., Eds. Chapman & Hall, New York (1996).

Lewis Sr, RJ (Ed.): Hawley's Condensed Chemical Dictionary, 13th ed. In: Comprehensive Chemical Contaminants Series CD-ROM. Van Nostrand Reinhold, New York (1997).

d) Reference Request and Literature Search Forms

Request for Journal Articles, Reports, and Studies

Name: _____Date: _____

Address for mailing photocopies:

Chemical/Agent: _____Total requested: _____

> >< < < < < < < < < < < < < < < < < < < < < < < < < < < <

Requests must contain the following information:

Journals
Journal name
Volume Number
Issue number [if available]
Page span
Year of publication
Author(s): Last name(s) and initial(s)
Title of Article

Reports/Studies
Title
Year of publication
Author(s): Last name(s) and initial(s)
Publisher/Company/Agency
Source of citation

> >< < < < < < < < < < < < < < < < < < < < < < < < < < < <

SEND TO:
The Science Group, ACGIH®
ATTN: K. Stewart

E-mail: science@acgih.org

FAX: 513-742-3355

Mail: ACGIH®
ATTN: K. Stewart
1330 Kemper Meadow Drive
Cincinnati, OH 45240-1634

Phone: 513-742-2020

e) Recommended References for Literature Searches

f) ACGIH® Conflict of Interest Policy

ACGIH® Policy and Process on Bias and Potential Conflicts of Interest

(Approved and Adopted by the Board of Directors, September 17, 2000)

This policy and process on bias and potential conflicts of interest has been established and implemented to safeguard the integrity and credibility of ACGIH® programs and activities. It applies to the Board of Directors, Committee Chairs and Committee members (including those serving as consultant members). The Policy's general approach in defining and addressing bias and conflicts of interest has been modeled after that used by the National Academy of Sciences for its scientific study committees.1

The ACGIH® mission and purpose is to advance worker health and safety through education and the development and dissemination of scientific and technical knowledge. ACGIH®, as a not-for-profit association, is a private organization that operates for public purposes. There is a fundamental obligation of those having decision-making authority within ACGIH® to act in the best interests of the organization and the public good, rather than in furtherance of personal interests or those of third parties.

Members of ACGIH® have an individual obligation for ethical professional practice. Industrial hygiene associations in the U.S. have adopted a common Code of Professional Ethics. Canon 4 of the Code clearly establishes that avoidance of conflicts of interest is a basic principle of ethical practice: "Industrial Hygienists shall avoid circumstances where a compromise of professional judgment or conflict of interest may arise."2

The bias and conflicts of interest policy is supported by other means of ensuring scientific accountability in the association's decision-making processes. ACGIH® exercises oversight and review of committee appointments and has developed procedures for internal and external review of committee recommendations. Each of these plays an important part in the protection of ACGIH®'s programs and activities from inappropriate influences.

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1 National Academy of Sciences. "Getting to Know the Committee Process". February, 1998.
2 Code of Ethics for the Practice of Industrial Hygiene. Adopted by ACGIH®, AIHA, AAIH, and ABIH.

About ACGIH® – Its Committee Process and Deliberations

Since its founding in 1938, ACGIH® has provided technical knowledge, advice and guidance on occupational health and safety in several different forms: written reports reflecting the consensus reached by committees of experts; symposia engaging large audiences in discussion of issues; proceedings from conferences and workshops; peer reviewed scientific manuscripts; and an array of educational publications.

Through the efforts of the committees, ACGIH® provides critical information and recommended practices to occupational hygienists worldwide. This history of sharing knowledge, based on careful study and independent judgement, has garnered international respect for ACGIH®. ACGIH® technical committees focus on a range of issues in occupational/environmental hazard assessment and control techniques (e.g., occupational exposure values for chemical substances and physical agents, biological exposure indices, bioaerosols, infectious agents, air sampling instruments, and industrial ventilation).

The ACGIH® committee process is characterized by the following:

- All members of committees and the Board of Directors serve in a voluntary capacity without compensation. Certain expenses, such as travel costs to attend meetings, may be reimbursed according to an established expense reimbursement policy.

- Members of ACGIH® committees and the Board of Directors serve as individuals and not as representatives of organizations or interest groups.

- The Board of Directors appoints committee members for terms that begin on January 1. Each year the Committee Chair makes recommendations to the Board on the addition, retention, and retirement of committee members.

- Committees function under the authority of the Board of Directors. Committee actions are typically in the form of recommendations to the Board.

- No official action of the Board of Directors or a committee can be taken unless a quorum is present.

- Under current ACGIH® policy, a committee may have no more than 25% of its members as Associate members.

- Committees are expected to be evenhanded and to examine all information dispassionately. One of the committee's primary roles is to separate fact from opinion and analysis from advocacy. Scientific standards are essential in evaluating all arguments and alternatives.

- Members of committees should strive for consensus, but not at the cost of substantially weakening their analyses and conclusions.

Bias and Conflict of Interest

The credibility of ACGIH® and a committee's recommendations can be weakened if members of the committee are perceived as being biased. It is recognized that each individual who is knowledgeable about a subject brings his or her own biases and experiences to any study or committee effort. Therefore, a basic intent of this policy is to ensure that biases are balanced and that conflicts of interest are eliminated in ACGIH® decision-making processes.

A further intent of the policy is to provide the framework for a common understanding of what constitutes bias and conflict of interest. The identification of such influences inherently involves the application of judgment. It is to be expected that a range of perspectives and interpretations will be voiced in the review of specific situations or relationships and their possible effect on a member's objectivity. The following definitions, taken from the National Academy of Sciences, will be used as a starting point in discussions and determinations on potential bias and conflict of interest:

> ***Bias*** is defined as views stated or positions taken that are largely intellectually motivated or arise from close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group.

> ***Conflict of interest*** is defined as any financial or other interest which conflicts with the service of an individual because it could (1) impair the individual's objectivity, or (2) create an unfair competitive advantage for any person or organization.

The *appearance* of a conflict of interest can be just as damaging as the existence of a real conflict. An apparent conflict of interest arises when a reasonable person, with knowledge of the relevant facts, would question the impartiality of the individual in the matter being considered.

Potential sources of bias and conflict of interest are significant issues that are taken into consideration in the selection of committee members and are re-examined periodically throughout their terms of service (see "ACGIH® Bias and Conflict of Interest Procedures"). At the time of appointment, each committee member is required to acknowledge that this policy has been received and read. All professional, consulting, and financial connections, as well as pertinent intellectual positions and public statements should be identified and described on the confidential form, "Potential Sources of Bias and Conflict of Interest – Acknowledgement and Certification."

An appointment is not finalized until a review of information regarding potential conflicts of interest and bias has been completed by –

- The Board of Directors for appointments to Committee Chair; or
- The Committee Chair for recommended appointments to committee membership.

As part of the process of becoming acquainted with one another and with the specific tasks and projects to be undertaken during the year, each committee conducts an annual closed session discussion on bias and conflict of interest. The purpose of this session is to allow members to share questions and concerns they may have and to identify to the whole committee any circumstance(s) or relationship(s) that could be viewed as a potential conflict of interest. This session also provides a regular opportunity for the committee chairs to review and highlight those issues that are most relevant to the committee's work. The Board of Directors also conducts an annual conflict of interest discussion in closed session.

Examples of the types of relationships that a member of the Board of Directors or a committee should disclose are listed below. This is not a comprehensive list. Because interpretations can vary from person to person concerning what situations constitute a potential conflict of interest, it is important that these relationships be identified and discussed within the Board and committees. In each of the examples below, the member is asked to disclose *only those relationships that have potential relevance to his or her own involvement in ACGIH® matters and decisions*. Sometimes these relationships may apply to a relative or other close associate of the member and therefore be relevant to the member as well.

- Owner, employee, or paid consultant to an organization or corporation that could be impacted by an ACGIH® recommendation or practice guideline.

- Significant financial interests (e.g., investments, loans, liabilities, etc.) in an organization or corporation that could be impacted by an ACGIH® recommendation or practice guideline or with which ACGIH® does business. (Excluded financial interests include personal mortgages, personal loans for vehicles or other furnishings, saving/checking deposit accounts, publicly available mutual funds not concentrated in a specific industry or sector).

- Recipient of a grant, award, or contract from an organization or corporation that could be impacted by an ACGIH® recommendation or practice guideline.

- Serve as an expert witness in judicial or regulatory proceedings.

- Serve on advisory or review panels of private corporations or non-profit organizations.

- Serve as an officer or member of the board of directors for a trade group or an organization related to ACGIH®.

- Acceptance of gifts, entertainment, or other favors from any individual or organization that does, or is seeking to do business with ACGIH®, or may be impacted by ACGIH®.

If a potential conflict becomes apparent, the member may be asked to be recused from participation on specific matters or issues before the Board of Directors or the committee (e.g., not participate in discussion or not vote or author documents). For more severe or extensive conflicts, the member may be requested to resign from the committee. Failure to disclose a relevant conflict of interest will result in dismissal from the committee. In some circumstances, an individual may continue to participate on the committee if the conflict of interest is promptly disclosed, and the Board of Directors has determined that the conflict is not relevant to the issues considered by the committee. When a question of balance arises, the usual procedure is to add members to the committee to achieve the appropriate balance.

Special Issues for Committees Involved in Risk Assessments

Most ACGIH® technical committees are involved in some aspect of assessing occupational risk or hazard. Many times, recommendations for risk management must be made when the available scientific information is incomplete or inconclusive. In these situations, it is essential that there is a clear and traceable path from the application of sound judgment, scientific principles, and assumptions to the committees' conclusions and recommendations. Committees may establish additional procedures, approved by the Board of Directors, to address specific bias and conflict of interest issues within their operations.

Of all ACGIH® committees, there are a few in which human health risk assessment is at the core of their activities – Chemical Substances Threshold Limit Value (TLV®) Committee, Physical Agents TLV® Committee, and the Biological Exposure Indices (BEI®) Committee. These committees must constantly evaluate incomplete or inconclusive data, and the collective experience and reasoned judgment of committee members become crucial factors in developing conclusions and recommendations. Conclusions based on scientific evidence and those based on informed judgment must be clearly distinguished. Special care is needed to explain how the committees arrived at their conclusions and any assumptions used should be explicitly identified and justified. These aspects of the committees' deliberations are explicitly described in the ACGIH® publication "*Documentation of the TLVs® and BEIs®*".

The committees that develop TLVs® and BEIs® employ a process that involves review of their proposed occupational exposure criteria by the public and scientific peers. New and revised TLVs®/BEIs® are published on a list giving *"Notice of Intended Changes*" (NIC).3 Proposed values are placed on the NIC list for approximately one year or longer to solicit any new information that may have a bearing on their appropriateness. This step in the process provides an important mechanism for ensuring the committees' findings are objective, balanced and based on all available information that is scientifically valid.

3 The Notice of Intended Changes is published annually in the TLV® and BEI® Book, in the ACGIH® newsletter *Today*!, and on the ACGIH® Website (www.acgih.org).

Confidentiality and Public Access

Procedures and practices have been developed to protect committees from outside pressures and thereby safeguard the credibility and integrity of their work. Committee meetings, particularly as the committee gathers information, may include invited individuals who are not members of the committee. However, meetings are closed when the committee is deliberating to develop its findings. The committee also meets in closed session when discussing financial and personnel matters. Closed meetings are not open to the public or to any person who is not a committee member or an official, agent, or employee of the ACGIH®.

Committee reports and recommendations are the product of ACGIH® and not of the committee alone or individual committee members. Committee deliberations, drafts of documents, tentative conclusions – all are confidential until approved or ratified by the Board of Directors. Committee members are expected to treat committee deliberations and draft products as confidential. Committee members should refer public requests for information to the headquarters staff.

"Potential Sources of Bias and Conflict of Interest" forms are treated as confidential documents and are maintained at the ACGIH® headquarters office. The forms are destroyed at the conclusion of the member's term of service on a committee or the Board of Directors.

Role of Staff

Each committee is assisted in its work by qualified staff members who provide a variety of services to the committee. The overall staff role is to help create an objective and productive atmosphere in which the committee's deliberations can take place. When the committee and staff form a close professional partnership, the work of the committee is productive and rewarding.

Examples of the services staff provides to the committee include coordinating meeting arrangements, record keeping and drafting of meeting minutes, distributing meeting materials, and fielding inquiries from the public. In addition, staff is responsible for ensuring that ACGIH® procedures and practices are followed, and that the committee stays on schedule and within budget.

Staff members can also assist with the many aspects of the committee's research and editorial activities, including researching, writing, integrating portions written by others, and ensuring consistent style and format. However, the conclusions and recommendations are those of the committee. Staff should not insert its personal views into the committee's conclusions or recommendations.

ACGIH® Bias and Conflict of Interest Procedures

For the Board of Directors:
Complete the form "Potential Sources of Bias and Conflict of Interest -- Acknowledgement and Certification" prior to installation as a Director or Officer.

Participate in a closed session discussion by the entire Board that is conducted at least annually.

Voluntarily and immediately disclose to the Board of Directors any circumstance or relationship that could be a real or apparent conflict of interest.

Questions on an individual board member's real or apparent conflict of interest will be referred to the Board Chair for resolution.

For Committee Chairs:

Complete the form "Potential Sources of Bias and Conflict of Interest -- Acknowledgement and Certification" prior to initial appointment as Committee Chair.

Conduct a closed session discussion by the entire committee at least annually and ensure all committee members participate.

Recommend action by the Board of Directors to appoint or terminate membership on a committee.

Voluntarily and immediately disclose to the Board of Directors any circumstance or relationship that could be a real or apparent conflict of interest.

Questions on a Committee Chair's real or apparent conflict of interest will be referred to the Board of Directors for resolution.

For Committee Members:

Complete the form "Potential Sources of Bias and Conflict of Interest -- Acknowledgement and Certification" prior to appointment to the committee.

Participate in a closed session discussion by the entire committee that is conducted at least annually.

Voluntarily and immediately disclose to the Committee Chair any circumstance or relationship that could be a real or apparent conflict of interest.

Questions on a Committee member's real or apparent conflict of interest will be referred to the Committee Chair for resolution.

Adhere to any supplemental bias and conflict of interest procedures established for the committee.

POTENTIAL SOURCES OF BIAS AND CONFLICT OF INTEREST
ACKNOWLEDGEMENT AND CERTIFICATION

BY SIGNING THIS FORM, I ACKNOWLEDGE AND CERTIFY THAT –

1) I HAVE RECEIVED A COPY AND I HAVE READ THE ACGIH® "POLICY AND PROCESS ON BIAS AND CONFLICTS OF INTEREST".

2) I HAVE TRUTHFULLY AND TO THE BEST OF MY KNOWLEDGE IDENTIFIED AND VERBALLY DISCLOSED ALL POTENTIAL SOURCES OF BIAS AND CONFLICT OF INTEREST THAT COULD BE ASSOCIATED WITH MY ACGIH® ACTIVITIES AND WILL DO SO AS THESE MAY ARISE IN THE FUTURE.

3) THE INFORMATION I SUPPLY IS SOLELY FOR THE CONFIDENTIAL REVIEW BY ACGIH® AND I DO NOT AUTHORIZE FURTHER DISCLOSURE OR RELEASE OF ANY OF IT FOR ANY OTHER USE.

NAME:	ACGIH® POSITION:
SIGNATURE:	DATE:

g) Symposium Timetable

1. Written proposal to Communications Subcommittee Chair
2. Subcommittee reviews, determines relevance to TLV® process, and makes written recommendation to Steering Subcommittee.
3. Steering Subcommittee reviews, seeking input as necessary, and makes a written recommendation to the Education Director.
4. The Education Director will review the proposal and Committee recommendation.
    a. If the Committee has approved the proposal and the Education Director decides to go forward with planning, the Steering Subcommittee will identify a task force to work with the Education Director. The task force will report regularly to the Steering Subcommittee and will seek input and ideas from the Committee, as necessary.
    b. If the Committee has not approved and the Education Director decides to proceed, individual members of the TLV® Committee may participate in planning activities, but will do so as individuals, not as members of the TLV® Committee. Sponsors and attendees will be informed that the TLV® Committee is not formally interested in the symposium and has not been a formal participant in its planning or execution.

h) Symposium Proposal Form

1. Purpose of symposium - statement delineating what is of interest to TLV® deliberations and why

a. Topics relevant to agents under study will receive higher priority. Agents on the Notice of Intended Change may be considered, but there must be compelling scientific reasons.

b. Presentation of new information that facilitates setting of TLV® using best available data and scientific judgment

2. Description of expected participants

3. List of potential sponsors

i) Committee Organization Chart