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Defining the Science of Occupational and Environmental Health<sup>®</sup>

## **OPERATIONS MANUAL**

# **BIOLOGICAL EXPOSURE INDICES (BEI<sup>®</sup>) COMMITTEE**

**Approved by the ACGIH<sup>®</sup> Board of Directors: June 4, 2017**

## **Committee Mission**

The Biological Exposure Indices (BEI<sup>®</sup>) Committee is appointed by the Board of Directors of ACGIH<sup>®</sup>. The issuance of BEIs and their supporting *Documentation* is the principal mechanism for the dissemination of these guidelines, although the Committee may also develop more general positions, instruction materials, educational media, or topical symposia to focus on issues of concern. This Committee's vision is to be a respected, worldwide leader in the development and dissemination of occupational health-based biological exposure guidelines.

The mission of the BEI Committee is to recommend biological exposure guidelines for use in the practice of industrial hygiene and by other qualified professionals to protect worker health. BEIs are based on the best available data and, whenever possible, peer-reviewed literature.

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

- Scientifically valid and supported by professional judgment
- Leading edge
- Well documented (i.e., based on the review of peer-reviewed, scientific literature)
- Understandable and clear
- Produced by a clearly-defined process that is balanced and free of conflict of interest

The BEI Committee operates under the Bylaws of ACGIH and the administrative policies and procedures approved by the ACGIH Board of Directors.

## **Membership**

### ***Eligibility***

The Committee may have up to 20 members representing the disciplines necessary for establishing BEIs. A range of professional affiliation is necessary to ensure a balance of disciplines; however, the Committee will consist of a simple majority of members professionally affiliated with academia or government. Committee members serve in their individual capacity and do not serve as representatives of their organization or their employer. Each member of the Committee will have full voting rights for the purposes of the business of the Committee. Committee leadership (Committee Chair and Vice Chair) must be Voting Members of ACGIH. A voting member of ACGIH shall be a professional who currently spends greater than 50% of his or her employment in the field of Occupational and Environmental Health and Safety, a professional who has retired from employment that involved greater than 50% of his or her time in the field of Occupational and Environmental Health and Safety, or a full-time student officially matriculated in an undergraduate or graduate program in environmental health, occupational health and safety or related discipline.

### ***Member Selection***

Individuals interested in joining the Committee will be asked to complete an application ([Appendix A](#)) and provide a current resumé or curriculum vitae. The Committee will review these documents and determine whether the applicant is eligible and has qualifications that fit the current needs of the Committee.

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

- Disciplinary training and education
- Professional background
- Past relevant experience
- Personal attributes necessary to meet Committee goals

The following criteria will be used to assess the overall membership of the Committee and each new member applicant:

- The Committee should have a mix of persons who have expertise in one or more of the following: occupational medicine, epidemiology, toxicology, industrial hygiene, analytical chemistry, or other related specialties (e.g., statistics, etc.).
- Preference will be given to individuals with 10 or more years of professional experience, with multi-disciplinary backgrounds, and with an advanced degree in his or her field of expertise.

- Individuals should demonstrate effective writing capabilities and communication skills through publications, presentations, and/or other activities.
- The membership should reflect the demographics of the industrial hygiene and occupational health field.

Any individual interested in volunteering on the BEI Committee will be sent an application form by staff. Applicants will be informed of membership expectations and responsibilities of the BEI 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. Complete applications and resumés/curricula vitae will be forwarded to the Chair of the BEI Committee.

The Committee members will be notified by the Chair of the names of applicants under consideration. The Chair will ask the Committee members for an assessment of the applicant. The Committee will review and consider all new applicants at least once per year, or more frequently if necessary. If the Committee agrees the applicant is acceptable and there is continued interest between both parties, the Chair will assess each application considering all Committee feedback and forward to the ACGIH Board of Directors those name(s) he/she recommends for approval to appoint as a member candidate. After Board approval, the Chair may extend an invitation to the member candidate to attend and participate at the next Committee meeting. The Chair will identify and assign responsibilities to the member candidate during his/her candidacy period. These responsibilities will include the assignment of a *Documentation* or BEI feasibility assessment to be developed as a draft, administrative activities, or other duties.

The Chair will solicit input from all Committee members concerning membership for member candidates that successfully complete their candidacy period. The BEI Committee Chair will evaluate each member candidate and make the final decision concerning a recommendation for membership. Names and resumés/curricula vitae of recommended member candidates will then be forwarded by the Chair to the ACGIH Board of Directors for a decision regarding approval and formal appointment.

Should a member candidate not fulfil the criteria of membership, a letter will be sent by the BEI Committee Chair thanking the member candidate for his/her interest. Should a member candidate not be selected for other reasons, a letter will be sent by staff thanking the person and asking for interest in remaining in the pool of applicants for future consideration.

### ***Responsibilities and Expectations***

The BEI Committee follows the Membership Expectations and Responsibilities requirements as described in [Appendix B](#).

BEI Committee members are expected to contribute to the work of the Committee. This may include time spent annually preparing and developing BEI *Documentation*, reviewing *Documentation*, attending scheduled face-to-face meetings and participating in scheduled teleconferences. These expectations may vary for individual members, depending on other activities undertaken within the Committee. Individual members will negotiate their activities with the Committee Chair. More senior members will also be expected to provide guidance and mentorship to new members.

Members are expected to comply with all policies and procedures of ACGIH. 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 ongoing productivity, participation and collegial behaviour. When considering reappointment, 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 *Documentation* and other activities as needed.

## ***Terms***

Members are expected to serve a three year term contingent upon a review of accomplishments and annual re-appointment by the ACGIH Board of Directors. Membership terms begin on January 1. The Committee Chair may consult with the members of the Committee prior to recommending appointment. Expectations for continuing membership include:

- Attendance at and constructive contributions to meetings;
- Participation in scheduled conference calls;
- Satisfactory progress in completing assignments, as recorded in meeting minutes and the Committee work plan, including but not limited to preparing and reviewing *Documentation* each year.

Member contributions to the work of the Committee and progress on assignments will be evaluated on an annual basis by the Committee Chair in consultation with the Vice Chair and vetted by the Committee throughout the year.

## ***Member Candidates***

The BEI Committee may choose to invite potential members to participate in Committee activities as “member candidates” before recommending them for formal appointment. This practice allows the potential member to understand the role of Committee members, and allows the Committee to evaluate the potential member. The Board of Directors must approve individuals before they become member candidates. Member candidates do not have voting privileges for purposes of Committee business but are expected to participate in Committee activities, attend meetings of the Committee, and will be expected to participate fully in Committee discussions. Member candidates are expected to complete a minimum one year candidacy period before being eligible for full membership and are expected to follow all ACGIH policies and procedures.

## ***Consultants***

Periodically the Committee may need specialized technical expertise or assistance in completing a particular BEI and utilize the help of volunteer consultants to the Committee to fill that void. These consultants are identified and vetted by Committee members, in a similar fashion to member candidates and nominated by the BEI Chair for review and appointment by the ACGIH Board of Directors. Consultants are utilized when the expertise is temporarily needed and is not present within the current committee membership. Consultants do not have voting privileges and attend meetings only at the invitation of the Chair.

## ***Awards***

### **WILLIAM D. WAGNER AWARD**

The William D. Wagner Award was established in 2003 and is presented annually to honor any person in the field of national and international worker health and safety who has been an outstanding example of commitment and dedication to the creation and dissemination of occupational exposure values (OEVs). The award recipient will be chosen by the BEI Committee, on a rotating basis, with the other two standing ACGIH OEV Committees (Threshold Limit Values for Chemical Substances, Threshold Limit Values for Physical Agents).

Every third year, the BEI Committee will submit a recommendation to the Board of Directors regarding appointment of the award recipient. The award will be presented at one of the meetings of the BEI Committee and the awardee will be invited to speak to the BEI Committee on some aspect of national and international health and safety. Funds to support the travel for the recipient will be determined by the Board of Directors and managed through ACGIH.

## Committee Structure

### *Position Descriptions*

#### **BEI COMMITTEE CHAIR**

**Method of Selection and Appointment:** The Chair is nominated through an internal committee selection and vote process, the results of which are recommended to the Board for final approval. Potential candidates may be the Vice Chair, current Committee members or qualified individuals from outside the Committee. Candidates must meet membership criteria of the Committee and be a Voting Member in good standing of ACGIH. The Committee will screen the nominees and may choose to ask for additional information (e.g., position statement) to aid the screening process. All Committee members will be asked to vote for one of the nominees. The Committee Chair and Vice Chair will tally the votes (with assistance from staff). The slate of nominees and number of votes received by each nominee will be forwarded to the Board of Directors for approval.

The Chair will hold the appointment for a term of three years. This appointment may be renewed for more than one term. The Chair will hold the position contingent upon annual re-appointment by the Board of Directors.

**Succession:** If the Chair position becomes vacant, the Vice Chair shall assume the role of Chair and shall serve the remainder of his/her predecessor's term. At the end of the term, a Chair will be selected following the selection and appointment process described above.

**Duties:** The Chair leads the BEI Committee and works closely with the Vice Chair to ensure the Committee's progress toward fulfilling its mission and goals. The Chair:

- assists and oversees Committee activities, including conducting Committee meetings.
- oversees budget management, spending, meeting plans (with assistance from staff).
- monitors overall workload and makeup of the Committee.
- assures regular, clear communications with staff and Board of Directors by interacting with the Board Liaison, staff, or Board members, as necessary.
- assures regular, clear communications with external parties by reviewing all comments received and providing input to replies sent by staff.
- assures communication between all members of the Committee and that the Committee is functioning according to guidelines and policies. Consults regularly with the Vice Chair to assure proper functioning of internal Committee activities.
- represents the BEI Committee to outside parties in accordance with the ACGIH Public Affairs and Communications Policy.
- represents the BEI 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.

#### **BEI COMMITTEE VICE CHAIR**

**Method of Selection and Appointment:** The Committee Chair, after consultation with the Committee, recommends the Vice Chair to the Board of Directors, which approves the recommendation and appoints the Vice Chair. The Vice Chair will hold the appointment for a term of three years. The appointment may be renewed for more than one term. The Vice Chair must be a Voting Member in good standing of ACGIH and will hold the position contingent upon annual re-appointment by the Board of Directors.

**Duties:** The Vice Chair is responsible for assisting the Chair in assuring that internal Committee functions are adequately carried out. The Vice Chair:

- assists the Chair as necessary.
- assists the Chair to oversee internal Committee activities that support *Documentation* preparation and membership.
- serves to fulfil the responsibilities of the Chair when s/he is unable or unavailable to do so.

**Reporting:** The Vice Chair will report to the Chair of the Committee on his/her individual activities.

## Conflict of Interest

The BEI members, member candidates and consultants, hereafter referred to in this section as “Members”, are required to follow the ACGIH Policy and Process on Bias and Potential Conflicts of Interest, published on the website at <http://www.acgih.org/tlv-bei-guidelines/policies-procedures-presentations/conflict-of-interest-policy>.

Any “Member” with a potential, real, or perceived conflict of interest or bias with respect to a chemical substance or issue under consideration by the Committee must orally disclose the conflict of interest before the entire Committee. In addition, a written declaration must be completed at the same time. This declaration is required annually and when material changes in their status occur. Members should review all of the details of this policy. Information relevant to the BEI 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.

Through participation in a closed session discussion, every member of the Committee will be asked to orally describe before a quorum of the voting Committee membership, relevant information concerning his/her background, current employment and professional activities, consultancies, financial holdings, and research funding. In addition, the member should orally disclose any relevant publications history and identify any technical biases. This closed session discussion will occur at least annually and will focus on all activities and associations that may have relevance to the activities of the Committee. The BEI 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, the Committee Chair will begin the review of new substances with a request for notification of Conflict of Interest from the Committee members. In addition, any member who develops a new conflict of interest for an ongoing chemical *Documentation* will be expected to notify the other members of the Committee.

It may not always be in the best interests of the BEI Committee for a member who has a significant conflict of interest to remove him or herself entirely from the BEI development process when s/he is very knowledgeable about that particular substance. In such cases, the Chair will work directly with a member to assure this conflict is minimized while allowing for the fullest participation practical. If a member who works for an entity with a direct interest in a substance undertakes the initial authorship of a *Documentation* concerning that substance, a variety of paths may be utilized to address and minimize 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*.
- review by an expert external to the Committee (the latter is recommended only rarely).

Open and free discussion of conflict of interest is key to this process. All Members who have participated fully in the BEI 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 the conflict cannot be eliminated or removed to the satisfaction of the Committee, members may need to recuse themselves from any discussions and reviews, and must excuse 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 Committee. The Chair will conduct a review with the Committee and make a recommendation to the Board. Depending on the status of the BEI (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.

## **BEI Production Guide**

### ***Voting Procedures***

The Committee follows the ACGIH Committee Voting Procedures as described in [Appendix C](#).

### ***BEI Development Process***

The BEI Committee follows the TLV/BEI Development Process, posted on the ACGIH website at: <http://www.acgih.org/tlv-bei-guidelines/policies-procedures-presentations/tlv-bei-development-process>.

## **UNDER STUDY**

Substances/issues are initially assigned to the Under Study list by a consensus of the voting Committee membership and can be added to or removed from the list throughout the year, as appropriate. A variety of factors are used in this selection process, including prevalence, use, number of workers exposed, availability of scientific data, existence/absence of a BEI, age of a BEI, input from the public, etc. Once a substance or issue has been identified by the Committee for review, a list of substances/issues under study are published by February 1 each year in the *ACGIH Annual Reports of the Committees on TLVs and BEIs*, the annual *TLVs and BEIs* book, and on the ACGIH website (<http://www.acgih.org/tlv-bei-guidelines/documentation-publications-and-data/under-study-list>). This Under Study list is published to serve as notification to stakeholders and to solicit comments and data. Changes to the Under Study list are posted on the ACGIH website.

The Under Study list is updated by July 31 into a two-tier list. Tier 1 indicates which substances/issues may move forward as a Notice of Intended Change (NIC) in the upcoming year, based on their status in the development process. Tier 2 consists of those substance/issues that will not move forward, but will either remain on, or be removed from the Under Study list for the next year. This list will remain in two-tiers for the balance of the year. Substances/issues added to the Under Study list after publication of the two-tier list will be placed on tier two.

Once a substance is placed under study by the Committee, a member or member candidate may be assigned the task of preparing a Feasibility Assessment. Feasibility Assessments provide a brief report of the evaluation of the available scientific literature that may serve as a basis for a possible new BEI recommendation.

## **FEASIBILITY ASSESSMENTS**

Extensive data of good quality are needed to develop a BEI; therefore the feasibility assessment is critical to the efficient use of Committee resources. The criteria for feasibility will generally include, but may not be limited to:

- the number of industries using the agent and the number of workers exposed.
- the availability and quality of data that relate any proposed biological indicators to exposure conditions or to health outcomes.
- the routes of exposure, with special emphasis on inhalation and dermal contact.
- the routes of elimination, emphasizing the type of specimen to be collected.
- the severity of the health risks associated with exposure.
- the availability and utility of analytical methods for measuring the determinant in the sample.

If the judgment of the Committee, after discussing the feasibility report, is affirmative, the author of the report is generally assigned to proceed with development of a proposed new BEI and *Documentation*. Another member of the Committee may be assigned as author, co-author or reviewer at the discretion of the Chair.

If the judgment is negative, a summary of the report is prepared. The report and summary are then presented to the Committee by the contributing Committee member(s). The Committee may then make a motion to approve the report and summary. If the motion is seconded, the Committee will review/critique the report and summary and subsequently vote on the proposed action. If the vote is approved, the report and summary are placed on file at ACGIH and the substance is listed in the BEI section of the *TLVs and BEIs* book under Feasibility Assessments.

The summary is then made available to all interested stakeholders and is intended to encourage the development and publication of new data. Therefore, the negative feasibility assessment should identify the important shortcomings of the existing information. Public requests for summaries of negative feasibility assessments should be made to the ACGIH Science and Education Group at [science@acgih.org](mailto:science@acgih.org).

#### **DRAFT DOCUMENTATION**

One or more Committee members are assigned the task of collecting information and data from the scientific literature and preparing a draft *Documentation*. The draft *Documentation* is reviewed and critiqued by the other Committee members. This may result in several revisions to the draft *Documentation* before the Committee accepts the proposed BEI. Draft *Documentation* are not available to the public during this stage of the development process.

Once the proposed BEI and draft *Documentation* are accepted by the Committee, a motion may be proposed to place the draft on the NIC. If the motion is seconded, the Committee will discuss and vote on the proposed action. Voting requires a quorum of the voting Committee membership present (greater than 50%). If the vote is approved, the Committee's recommendation is then sent to the Board of Directors for review and ratification. If ratified by the Board, the BEI and any notations are listed on the NIC and the *Documentation* is published by February 1 each year.

#### **NOTICE OF INTENDED CHANGES (NIC)**

The NIC is a listing of the proposed actions of the BEI Committee. Following the NIC ratification by the Board of Directors, interested parties are invited to provide data and substantive comments, preferably in the form of peer-reviewed scientific literature. A proposed BEI and its draft *Documentation* are held on the NIC for a minimum of one year to allow for public review. The comment period for an NIC draft *Documentation* and its respective BEI(s) and any notation(s) is limited to a firm 4-month period running from February 1 to May 31 of each year. As general practice, the BEI Committee reviews all submissions of comments regarding substances/issues on the Under Study list, as well as NICs, or currently adopted BEI(s). Because of the time required to properly review, evaluate, and consider comments during the fall meetings, any comments received after the May 31 deadline may not be considered in that year's Committee deliberations regarding the outcome for possible adoption of an NIC draft. Any comments regarding an NIC draft BEI *Documentation* received after the May 31 deadline will be fully considered in the following year. If the Committee finds or receives substantive data and/or comments that change its scientific opinion regarding a BEI value or notation(s), the Committee may revise the proposal(s) and make a motion to recommend to the Board of Directors that it be retained on the NIC the following year. If the motion is seconded, the Committee will review/critique the draft *Documentation* and subsequently vote on the proposed action for the matter to be retained. If the vote is approved, the Committee's recommendation is then sent to the Board of Directors for review and ratification. Draft *Documentation* are published annually and made available through the ACGIH Customer Service Department ([customerservice@acgih.org](mailto:customerservice@acgih.org)) or online at <http://www.acgih.org/forms/store/CommercePlusFormPublic/search?action=Feature>.

#### **ADOPTED DOCUMENTATION**

If the Committee neither finds nor receives any substantive data that change its scientific opinion regarding an NIC BEI (or notation) and its *Documentation*, the Committee may then make a motion to recommend to the Board of Directors that the matter be adopted. If the motion is seconded, the Committee will review/critique the draft *Documentation* and subsequently vote on the proposed action. If the vote is approved, the Committee's recommendation is sent to the Board of Directors. Once ratified by the Board, the BEI is published as adopted in the *Annual Reports of the Committees on TLVs and BEIs*, in the annual *TLVs and BEIs* book, and the draft *Documentation* is finalized for formal publication.

## WITHDRAW FROM CONSIDERATION

At any time while a substance/issue is on the NIC, the Committee may determine not to proceed with the development of a BEI and make a motion to withdraw it from further consideration. If the motion is seconded, the Committee will review/critique the proposed action and subsequently vote on the matter to be withdrawn. If the vote is approved, the Committee's recommendation will be sent to the Board of Directors for review and ratification. If ratified by the Board, notification of the withdrawal will be made in the *Annual Reports of the Committees on TLVs and BEIs* and in the *TLVs and BEIs* book.

Substances/issues that have been withdrawn from consideration may be reconsidered by placement on the Under Study list.

Substances/issues that are currently adopted by the Committee can be recommended for withdrawal by placement on the Under Study list and following the NIC adoption process described above.

Substances/issues on the Under Study list can be withdrawn from consideration by a consensus of the voting Committee membership.

### ***BEI Feasibility Assessment and Documentation Guidelines***

The purpose of the BEI *Documentation* is to clearly describe, present, and interpret the appropriate scientific information supporting the derivation of the BEI and its associated notations for a given chemical. It should be kept in mind that BEI *Documentation* are not a complete review of all the literature available on a particular substance. The *Documentation* provides the pertinent scientific information and data with reference to the literature sources that were used to derive the BEI value and notations for the purpose of protecting employees in the occupational setting. The primary users of the BEI *Documentation* are occupational hygienists and other occupational health professionals.

BEI Feasibility Assessment and BEI *Documentation* templates can be found in [Appendix D](#) and [Appendix E](#), respectively.

### ***Literature Search***

For new and revised BEIs, the Committee member should conduct a full literature search using the appropriate databases. Basic references (a list is included in [Appendix F](#)) should be consulted. Staff or other Committee members may provide assistance with acquiring those references to which a member does not have access.

For BEIs requiring revision, the Committee member should request an electronic copy of the current BEI *Documentation* from ACGIH and any references on file. A full literature search should then be conducted using databases and references listed in [Appendix F](#).

Primary references should be relied upon whenever possible. Secondary sources such as books and reviews may be used for an overview of the data. Members are encouraged to use local libraries; however, if such access is difficult they may request that 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 all BEI *Documentation*, particularly for the justification of the BEI. If non-peer-reviewed materials are necessary, the member should discuss this with the Committee Chair. If these references are considered necessary, the information should undergo some form of peer review to determine their acceptability. It will be up to the Committee Chair to determine the nature of peer review that is appropriate; for example, an internal committee peer review to ensure that accepted scientific methods were used to obtain and analyze the data and that no real or perceived biases exist. The member is expected to provide a copy of these materials to ACGIH upon completion of the draft *Documentation*. If unpublished data are used, the owner of the data must first provide ACGIH written permission to use, cite, and release the data/report to an outside party upon request.

In the case of translated information, care must be taken to ensure the information has been properly interpreted. Translation of non-English sources may be possible, if the study is critical to the BEI recommendation. The need for such translation should be discussed with the Committee Chair; such requests should then be sent to the ACGIH Staff. Copies of translations should be sent to staff to be filed at ACGIH.

If information is contained in a government or industry document, it should not be assumed that it has undergone peer review.

## Communications

The BEI Committee follows the ACGIH Public Affairs and Communication Policy posted on the ACGIH website at <http://www.acgih.org/docs/default-source/Policies/acgihpubaffairscommpolicy.pdf?sfvrsn=0>.

### *External to ACGIH*

The Committee recognizes that there are many different parties with an interest in the BEI process and its outcomes. At the same time, it is important that these external parties not compromise the Committee's decision process, which is based primarily on peer-reviewed scientific information. Thus, it has established written policies and procedures that allow input from external parties to the Committee concerning substances currently under review. These policies and procedures are described below.

External parties are encouraged to submit their comments and input to the Committee in writing. The appropriate method for an interested party to contribute to the development of a BEI is through the submission of literature that is peer-reviewed and public and not to rely on unpublished studies as their input into the process. Comments and requests should be sent in electronic format, via the ACGIH Science and Education Group at [science@acgih.org](mailto:science@acgih.org).

The Committee may receive requests from external parties to make a presentation about specific substances or issues. It is *strictly by exception* that such requests are granted. The Committee focuses on data that have been peer-reviewed and published and not on data presented in a private forum. The Committee may grant such a request when the data are significantly new, have received peer review, are the best vehicle for receipt of the information, and are essential to the Committee's deliberations. The presentation is not a forum to voice opinions about existing data. Requests for this type of presentation must be submitted in writing, which at a minimum, addresses the following elements: (a) a detailed description of the presentation; (b) a clear demonstration of why the information is important to the Committee's deliberations; and (c) a clear demonstration of why a meeting is the necessary method of delivery. This request must be sent to the ACGIH Science and Education Group at [science@acgih.org](mailto:science@acgih.org). Staff will forward the request to the Chair and other appropriate Committee members for consideration. A formal invitation to present, if desired, will be extended by the Chair and communicated through the ACGIH Science and Education Group, after a review of the submitted request.

The preferred venue for presentation of new data is an ACGIH sponsored symposium or workshop that provides a platform for public discussion and scientific interpretation. ACGIH accepts suggestions on symposium topics, including suggestions about sponsors, speakers and format. Suggestions should be sent, in writing, to the ACGIH Science and Education Group at [science@acgih.org](mailto:science@acgih.org). See [Appendix G: Symposia and Workshops](#) for more information.

The BEI Committee communicates with its stakeholders by publishing its decisions as *Documentation*, following a clearly delineated process. Authorship of *Documentation* is a confidential matter. Such authorship may not be discussed with any person external to the Committee. Methods for seeking information from external parties while ensuring anonymity should be discussed with the Committee Chair and performed through the ACGIH Science and Education Group. Information, materials, *Documentation* prior to publication on the NIC, etc. may not be shared with anyone external to the Committee. *Documentation* prior to publication on the NIC can be shared with other ACGIH Committees once approved by the Chair. The BEI Committee is under no obligation to inform any particular group about its activities or decisions.

### **GUEST PARTICIPATION AT MEETINGS**

The BEI Committee may invite outside speakers to its meetings for the purposes of sharing experience and expertise, to add an additional or international perspective to development of a BEI and its *Documentation*, or to present data and research. BEI Committee meetings are closed to the public and outside speakers are not permitted to participate in BEI Committee deliberations. The meeting minutes will reflect when guests were present and detail the extent of their participation.

### *Internal to the Committee*

The BEI Committee relies on meeting minutes for documenting its activities and tracking its progress. Formal minutes will be taken at all Committee meetings, generally by the staff. These minutes are used to document the activities and formal votes of the Committee (without identification of individual names, except for abstentions due to Conflict of Interest). Copies will be sent to all members of the Committee and the Board Liaison.

### ***Communications between the Committee and ACGIH***

The Committee assures timely and consistent communication with ACGIH through its Staff and Board liaison. The staff liaison or other staff member(s) attend all Committee meetings. Staff communicates regularly with the Committee Chair about Committee activities. Staff works closely with the Committee Chair on all issues, including budgeting and spending, meeting arrangements, publications, communications with external parties, etc.

The Board Liaison attends 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.

Staff will work with the Committee Chair and Vice Chair to facilitate effective communication between the TLV-CS Committee and with the Board. For example, ensuring the actions of the BEI and TLV Committees are in concert with each other prior to approval of the actions by the Board.

### **Education and Outreach**

A goal of the BEI Committee is to foster educational and outreach activities. This includes reviewing and developing ideas and plans for future symposia (scientific presentations) and workshops (educational forums). For internal educational purposes and activities, the Committee will seek input from all BEI Committee members and the staff liaison when deciding topics. For external educational and outreach activities, the BEI Committee will work closely with the ACGIH staff when formulating its ideas. The ACGIH Education Event Planning Worksheet found in [Appendix H](#) should be completed in conjunction with staff for use in developing any external education event. External activities require review and approval from the Committee prior to their implementation.

### ***Communication with Groups That Set Occupational Exposure Values***

As part of its outreach initiatives, the BEI Committee may undertake as one of its goals regular communication and interaction with other national and international groups responsible for determining occupational exposure guidelines. When communicating and interacting with these outside groups, the Committee will follow the policies and procedures as described in the ACGIH Public Affairs and Communication Policy. The BEI Committee Chair and staff liaison will work together to build and foster relationships with such groups.

**Appendix A: Membership Application**



1330 Kemper Meadow Drive Cincinnati, OH 45240-4148, USA  
Phone: 513-742-2020 Fax: 513-742-3355  
E-Mail: [mail@acgih.org](mailto:mail@acgih.org) <http://www.acgih.org>

Defining the Science of Occupational and Environmental Health®

## ACGIH® Biological Exposure Indices (BEI®) Committee Membership Application

Thank you for your inquiry into membership on the ACGIH® Biological Exposure Indices Committee. To assist the Committee in its review and selection of new candidates, please provide the following information and **submit your current resume and/or curriculum vitae**. Feel free to expand the size of this application as needed to accommodate responses larger than the space allocated.

**Applicant's Name:** \_\_\_\_\_

**Address:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Phone:** \_\_\_\_\_

**Cell:** \_\_\_\_\_

**Fax:** \_\_\_\_\_

**E-mail:** \_\_\_\_\_

1. Name of Employer: \_\_\_\_\_

If employed by a regulatory/government agency, do your current activities relate to the development or setting of occupational health standards?

\_\_\_\_\_ Yes          \_\_\_\_\_ No

If yes, please indicate how your activities relate to regulations or regulatory policies, and provide a list of substances or agents with which you have worked in relation to the development or setting of occupational health standards.

2. Check your area(s) of professional expertise. Use ++ for your major area(s) of expertise and + for minor area(s).

\_\_\_\_\_ Industrial Hygiene

\_\_\_\_\_ Occupational Medicine

\_\_\_\_\_ Epidemiology

\_\_\_\_\_ Toxicology

\_\_\_\_\_ Chemistry

\_\_\_\_\_ Other, please specify \_\_\_\_\_

3. Within your area(s) of professional expertise, do you have specific fields of specialization (e.g., field industrial hygiene, analytical chemistry, statistics, aerosols, carcinogenicity, risk assessments, etc.)? List up to three fields in which you consider yourself specialized or could provide particular expertise to the Committee.

4. How many years have you spent in your major area of professional expertise?

\_\_\_\_\_ < 5 years

\_\_\_\_\_ 11–20 years

\_\_\_\_\_ 5–10 years

\_\_\_\_\_ > 20 years

5. Check all relevant professional certifications you hold.

\_\_\_\_\_ CIH

\_\_\_\_\_ PE

\_\_\_\_\_ CSP

\_\_\_\_\_ DABT

\_\_\_\_\_ ROH

\_\_\_\_\_ Medical Boards, please specify: \_\_\_\_\_

\_\_\_\_\_ Other, please specify: \_\_\_\_\_

6. Check all degrees you hold:

BA       MA       DrPH       DVM       MD  
 BS       MS       ScD       VMD  
 MPH       PhD  
 Other, please specify: \_\_\_\_\_

7. Describe your writing and verbal communication experience.

8. Check the number of years of experience serving on professional and scientific committees.

< 3 years       6–9 years  
 3–5 years       > 9 years

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

10. Participation on the Committee requires a considerable amount of your time annually to attend committee meetings, participate on conference calls, write/review documents, and prepare/contribute to meetings. If you have questions about the time involved, please contact ACGIH® at the telephone number below. Do you have adequate time to devote to the activities of this Committee?

Yes       No

Please submit your application and current resume and/or curriculum vitae in one of the following three ways:

- Mail to the Chair of ACGIH® in care of the Headquarters Office at 1330 Kemper Meadow Dr., Suite 600, Cincinnati, Ohio 45240
- FAX to the Chair of ACGIH® in care of the Headquarters Office at 1-513-742-6170
- E-mail to the Chair of ACGIH® in care of the Headquarters Office at [science@acgih.org](mailto:science@acgih.org)

If you have questions, please contact ACGIH® at 1-513-742-2020.

**Thank you for your willingness to serve!**

**Appendix B: Expectations and Responsibilities of Members of the ACGIH® Biological Exposure Indices (BEI®) Committee**

- Each member is expected to make satisfactory progress toward completing Committee assignments, as documented in the meeting minutes.
- Members are expected to attend the meetings of the Committee. The duration of these meetings is generally 2–3 days. Members are expected to read meeting materials prior to the meeting and come prepared to contribute to Committee discussions and decisions.
- 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 of tenure on the Committee are expected to mentor and otherwise assist more recently appointed members and, at the request of the Chair, serve as members of other ad hoc committees.

## **Appendix C: ACGIH® Voting Procedure**

## ACGIH® Committee Voting Procedure

This procedure is not intended to be inclusive, but rather as basic information/instructions.  
Robert's Rules of Order serves as additional guidance.

### 1. Motion /Voting Process According to ACGIH® Practices:

- Establish a quorum. At ACGIH®, a quorum is a majority (> 50%) of the voting Committee members (hereafter referred to as members). Although Member Candidates and consultants are full participants in discussions, they do not have voting privileges.
- Assure that motions are presented clearly and concisely and that all Voting Members are aware of the exact language/intent of the motion (Note: Any motion that requires Board of Directors' approval must begin with a "Vote To Recommend (VTR) to the Board that . . .").
- Procedure for handling a motion:
  - Member (not Chair) makes motion ("I move that . . ."),
  - Another member seconds motion,
  - Members debate motion (When a motion is on the table, keep remarks to the motion under consideration),
  - Chair puts question to members for vote,
  - Chair announces result of vote.
- All members present have an obligation to cast a vote (Note: Chair only votes to make or break a tie).
- Recording motions and votes:
  - Identity of who makes or seconds a motion is not recorded in the meeting minutes.
  - The number of "YES" and "NO" votes is not recorded in meeting minutes.
  - ABSTENTION votes are recorded in the meeting minutes as follows:
    1. When ABSTENTIONS are for reasons other than conflict of interest (COI), the number of members abstaining is recorded, but not the names or reasons for the abstention. Abstentions should be rarely used unless for COI.
    2. When ABSTENTIONS are for conflict of interest, names of members abstaining for COI are recorded along with a note that the abstentions are for COI.

2. Matters that require a vote:

- Any Committee business that may require formal Committee approval, and/or approval by the Board of Directors. When in doubt, use the voting process.
- *Documentation* and their respective TLVs<sup>®</sup>, BEIs<sup>®</sup> and/or notations for substances or agents that are proposed for Committee approval (and Board ratification) to:
  - adopt as final,
  - add to NIC (and NIE: Physical Agents Committee),
  - retain on NIC (and NIE: Physical Agents Committee),
  - withdraw from NIC (and NIE: Physical Agents Committee), or
  - remove an existing substance or agent from the adopted TLV<sup>®</sup>/BEI<sup>®</sup> list (Note: If a proposal to remove is approved and ratified, the substance or agent must remain on the adopted TLV<sup>®</sup>/BEI<sup>®</sup> list and the proposed action so listed on the NIC for public notification and comment. The reason(s) for the proposed removal must be stated).
- *Documentation* for an adopted TLV<sup>®</sup> or BEI<sup>®</sup> that was significantly revised (A note should be added to the history section of the *Documentation* indicating the date and what type of change(s) was made.)
- Revision(s) to the *TLVs<sup>®</sup> and BEIs<sup>®</sup>* book (e.g., appendices, etc.) that may warrant public comment or an NIC (and NIE: Physical Agents Committee) listing.

3. Matters that do not require a vote:

- Revisions (i.e., additions or deletions) made to Under Study list.
- Editorial changes/updates made to adopted TLV<sup>®</sup>/BEI<sup>®</sup> *Documentation*, when such revisions are minor, supportive of the adopted value(s)/notation(s), non-controversial, etc. When such changes are made:
  - They should be brought to the Committee's attention.
  - A note should be added to the history section of the *Documentation* indicating the date and what type of change(s) was made.

4. Conditions that must be met before full Committee votes on Draft *Documentation* and their respective TLV(s)<sup>®</sup>, BEI(s)<sup>®</sup> and/or notation(s):

- The draft *Documentation* must be reviewed by the subcommittee (TLV<sup>®</sup>-CS Committee) or the author/co-author/assigned reviewer (TLV<sup>®</sup>-PA Committee, BEI<sup>®</sup> Committee, Bioaerosols Committee) and agreed upon that the *Documentation* with its numerical TLV(s)<sup>®</sup> /BEI(s)<sup>®</sup> and notation(s) are in order for full Committee final consideration/vote (Note: For the BEI<sup>®</sup>, TLV<sup>®</sup>-PA, and Bioaerosols Committees, this draft *Documentation* should include/address comments received from previous full Committee reviews).

- The draft *Documentation* with its numerical TLV(s)<sup>®</sup> /BEI(s)<sup>®</sup> and notation(s) must be in final (or near final) form and circulated in advance of the meeting to allow for full review by the Committee's members. The *Documentation* should be of sufficient quality to prevent the need for an inordinate amount of discussion or rushed review by the full Committee before vote.
- As needed, the principal author should be available to the Committee when the *Documentation* and its numerical TLV(s)<sup>®</sup> /BEI(s)<sup>®</sup> and notation(s) are up for Committee vote.

#### 5. Miscellaneous:

- Withdrawing or Modifying/Amending a Motion: Before a motion has been stated by the Chair, it can only be withdrawn or modified by the maker with agreement by the seconder. Once the motion is stated by the Chair, it can only be withdrawn or modified by general consent or a majority vote by the members.
- Motion to Reconsider: Hasty or ill-advised action can be corrected through the motion to reconsider. This motion can be made only by an individual who voted on the prevailing side and must be made on the same day or the next succeeding day after the original vote was taken (not counting a day which no business meeting is held during a session).
- Motion to Table: A Motion to Table can be made at any time an issue is before the Committee. The objective is to postpone the vote on the main motion. [The motion cannot specify a time for resumption; if it did, it would be equivalent to a motion to postpone definitely (which might be in order and even preferable.)] Such a motion is not in order when another member has the floor. The motion is not debatable, requires a second and a majority vote to pass. If passed, the issue before the Committee cannot be discussed further until another item has been considered and voted upon. Motions to Table are designed to be temporary in nature and merely reschedule the decision of an issue for a later time. When the Committee wishes to resume consideration of a tabled motion, any member may move to take a motion from the table. Such a motion requires a second, is not debatable, and requires a majority vote. If passed, the Chair announces the main motion and consideration is resumed. A tabled motion will expire if not acted on during the same session (if the group meets less than quarterly) or by the conclusion of the next session (if the group meets more than quarterly).
- Call the Question (Call the Vote): A Committee member may desire to have the vote taken before the Chair calls for the vote or before all members have finished discussing the issue. Rationale for this action could include moving a meeting along in a timely manner or determining how many members have already formed a conclusion. The motion (I call the question) is not in order when another member has the floor. The motion requires a second, is not debatable, and requires a 2/3 vote for passage. This vote determines if the discussion continues (No vote) or if the discussion ends (Yes vote). If passed, there can be no further discussion, and the Chair will ask for the vote on the motion under question. Note: Members must be very cautious about employing this method as it can restrict open dialogue.

**Appendix D: BEI Feasibility Assessment Template**

## *Feasibility Assessment Template*

# **Feasibility Assessment BEI<sup>®</sup> for [Insert Agent] [Date]**

### **Occupational Exposure**

(One or two paragraphs describing extent of exposure, identifying industries where the agent is used, routes of exposure, and any data on non-occupational exposure. When available, list the following:

OSHA Permissible Exposure Limit:  
Threshold Limit Value  
NIOSH Recommended Exposure Limit:  
ATSDR Minimal Risk Level:  
German BAT)

### **Health Risks**

(Two to three paragraphs on human and animal data, including occupational studies when available.)

### **Toxicokinetic Information**

(Describe uptake, metabolism, storage and elimination of parent compound and major metabolites. Emphasis should be on data in humans. Include data on partition coefficients and elimination half lives.)

### **Biological Sampling Issues**

(Comment on likely requirements for timing of samples, presence of interferences, methods for avoiding contamination, and sources of variability.)

### **Relationship of Biological Indicators to Exposure Guidelines**

(Discuss correlation between indicator and TLV<sup>®</sup>.)

### **Relationship of Biological Indicators to Health Risk**

(Discuss correlation between indicator levels and risk to health, where data are available.)

### **Summary (including judgment of feasible or not feasible)**

(One to two paragraphs, with recommendation on whether to proceed. General criteria for feasibility include substantial worker exposure or increasing trend, at least two human studies showing substantial agreement on toxicokinetics, existence of TLV<sup>®</sup> based on systemic

effects, availability of good analytical method for determinant, and absence of serious interferences, such as from background.)

### **Literature Cited**

(Typically 6 to 12 citations.)

**Appendix E: BEI<sup>®</sup> *Documentation* Template**

## **General Instructions for Preparing Main Body of the BEI<sup>®</sup> Documentation**

The primary purpose of the BEI<sup>®</sup> *Documentation* is to describe and analyze the scientific literature that specifically supports the derivation of a BEI<sup>®</sup> 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 data associated with a substance. To facilitate an organized description of this literature, the BEI<sup>®</sup> *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(ies) are most appropriate for consideration (i.e., weight-of-evidence analysis) in derivations of the BEI<sup>®</sup>. When a study seems to suggest the BEI<sup>®</sup> should be different from that selected, the reason for discounting this study should be provided.

Bibliographic references in the body of the draft *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., Absorption, Elimination, etc.) indicate this with the standard statement “No studies available”; if no data are available for a subheading (e.g., Pulmonary), 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 BEI<sup>®</sup> recommendation (adequate description of methodology, reported in peer-reviewed literature, evidence or reproducibility report, etc.). Use of unpublished information requires that the entire study or communication be on file at ACGIH<sup>®</sup> headquarters and that full disclosure must be transferred to ACGIH<sup>®</sup> so the Committee may cite these data as necessary to 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 BEI<sup>®</sup> 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 BEI<sup>®</sup> 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 Times New Roman font and the associated instructions for completion of each section are described in Arial. These are the font families used by ACGIH<sup>®</sup> to construct the TLV<sup>®</sup> *Documentation*. Make tables of data where possible using the table-making feature of Microsoft Word or WordPerfect.

## BEI<sup>®</sup> Documentation Template

**SUBSTANCE NAME** (use IUPAC convention, e.g., TRICHLOROETHENE)

CAS number:

Synonyms: (*local terminology, e.g., perchloroethylene*)

Chemical formula:

Chemical structure for organic compounds

### RECOMMENDED BEI<sup>®</sup>

Determinant	Sampling Time	BEI <sup>®</sup>	Notation
List in decreasing order of priority			

#### Basis for the Biological Exposure Index

- Brief summary of the rationale for the index or indices, including discussion of the relationship of each index to the TLV<sup>®</sup> and/or to dose–response information for human health effects.
- Indicate the specific health end-point addressed by the BEI<sup>®</sup> (e.g., narcosis, organ damage).
- In the case of multiple determinants, a brief discussion of their priority should be included.
- Briefly describe why (a) specific notation(s) is/are assigned.
- If the BEI<sup>®</sup> is a revision, include a short history of the BEI<sup>®</sup> and explanation for the revision.

#### Conversion Factors (DO NOT use bullets)

1 mg/L = XX mmol/L

1 mmol /L = XX mg/L

#### Uses and Properties

- One or two paragraphs describing the industrial settings where the material is used, together with an estimate of the number of workers exposed, if available.
- Properties should be limited to those relevant to biological monitoring, e.g., partition coefficients or other solubility data, saturation vapor pressure (check existing TLV<sup>®</sup> Documentation for other properties, but do not include those not specific for biological monitoring such as flash points, etc.).

#### Possible Non-occupational Exposure

One or more paragraphs, describing current data on non-occupational sources of exposure, as data provided. In particular, it will be important to assess the strength of non-occupational sources relative to workplace sources.

#### Absorption

- May be one paragraph or may be divided into the three categories below where data exist.
  - If divided into two or three categories, indicate which is(are) the dominant route(s) of exposure, e.g., “ABC is absorbed via respiratory, dermal, and gastrointestinal routes. Pulmonary absorption is the major route in the workplace.”
  - Indicate the kinetics of absorption for the different routes of exposure and an indication of the percent absorbed and the time it may take to reach a steady state concentration in the body.

## **Pulmonary**

## **Dermal**

## **Gastrointestinal**

### **Distribution**

- Provide a summary on the distribution of an agent, including such information as distribution rate, target organ/tissue, storage site, etc.

### **Elimination**

- Provide routes of elimination, and identify the principal route of elimination.
- Provide information on the rates of elimination. (In contrast to kinetics, this relates to the parent compound and how rapidly it is cleared from the body.)
- Describe whether elimination is the same or different when acute and chronic exposures are involved.

### **Metabolic Pathways and Biochemical Interactions**

- Describe the biotransformation of the agent, including chemical reactions, organs involved, metabolites or adducts formed, and any other interactions with host tissues or molecules.
- Provide figure illustrating metabolic pathways, if appropriate. If figure is acquired from a publication whose copyright is held by another corporate entity or individual, please provide the ACGIH® Staff with point-of-contact information so that permission-to-reproduce may be obtained.

### **Summary of Toxicology**

- Brief summary of the current knowledge of toxicology of the substance.
- Emphasize human data but include animal data where they support the conclusions for human toxicity.
- If the *TLV® Documentation* includes a detailed summary of toxicology, as it often does, the reader is referred there.
- Other substantial reviews such as those produced by ATSDR, EPA, NIOSH, OSHA, WHO, and others should be cited but not repeated.

### **TLV®-TWA or TLV®-C**

- Provide the TLV®-TWA or TLV®-Ceiling.
- Briefly describe the basis for the TLV®-TWA or TLV®-Ceiling and the health effect(s) being addressed.
- List any notations attached to the TLV®.

### **FIRST DETERMINANT (E.G., METHANOL IN URINE)**

### **ANALYTICAL METHODS**

- Provide acceptable method(s) with citation(s), e.g., high-pressure liquid chromatography (HPLC) method with ultraviolet detection.
- Specify if hydrolysis is required to release conjugates or not recommended for measure of the “free” metabolite. Specify any pre-treatment that may be necessary before instrumental analysis.
- Describe standard methods in current use, such as those by the BAT group. Mention a definitive method if available as the gold standard.

- Describe why a currently accepted method would be unacceptable, if data exist.

### **Sampling and Storage**

- Describe specimen collection, the type of container, and any preservatives/anticoagulants that may be necessary.
- Indicate preferred time of collection in relation to exposure and why.
- Indicate sample stability and temperature requirements for transportation to a laboratory.
- Indicate storage conditions to prevent deterioration if analysis may be postponed.
- Indicate stability of specimen under specified storage conditions if known.
- Indicate whether contamination of samples is possible, e.g., not possible if the determinant(s) are products of metabolism.

### **Biological Levels Without Occupational Exposure**

- Indicate whether significant amounts of the determinant(s) may be found in an occupational unexposed population, e.g., ambient background levels, alcohol consumption.

### **Kinetics**

- Indicate the elimination kinetics of ABC or the determinant(s), the potential for buildup during a week of repeated exposure and the recommended sampling time.
- Describe any toxicokinetic modeling data that support the elimination kinetics of ABC or its metabolites.

### **Factors Affecting Interpretation of Measurements**

- May be one or more paragraphs listing/describing what outside factors affect the determinant measurement. Section may be divided into the following three categories, where data exist.

#### ***Analytical Procedure and Sampling***

- Specifics of any required hydrolysis, advantages and detection limits of recommended methods, contaminants or co-exposures that may interfere with the analytical determination.

#### ***Exposure***

- Important points here are co-exposure to agents that (1) produce the same metabolite, (2) interfere with the metabolism of the determinant, and (3) impact ethanol consumption on the rate of metabolism of the determinant.

#### ***Population***

- Discuss any information concerning the influence of ethnic, cultural, genetic, or other factors that may differ across populations and would affect interpretation of the measurements.

### **Justification**

Provide discussion for the justification of the determinant or provide discussion under any or all of the following:

#### ***Toxicokinetic Approach***

- Describe briefly the linkage between the index and airborne concentration, or between the index and health risk, as the justification for the proposed value.

#### ***Field Studies (if data available)***

- Include numbers of subjects and controls, type of workplace, brief description of exposure assessment methods, use of PPE, and exposure results. Also include brief description of sampling and analysis parameters and an assessment, if available, of the expected value extrapolated to a typical workplace

exposure at the current TLV<sup>®</sup>-TWA.

**Laboratory Studies (if data available)**

- Include number of subjects and controls, type of exposure conditions, duration of exposure and route, nature of workload if not at rest, and an extrapolation to a typical workplace exposure at the TLV<sup>®</sup>-TWA.

**Simulation Studies (if available)**

- Toxicokinetic modeling that supports the proposed value should be described, including a brief discussion of the important assumptions and parameters used in the model. Experimental data that support the model are especially valuable.

**Other Subheadings (as appropriate)**

**Summary**

- One to two paragraphs summarizing preceding paragraphs for this determinant with an assessment of whether available data are sufficient to support a BEI<sup>®</sup> — usually the answer is “yes,” but it may be “no” where data are ambiguous and another determinant is proposed.

**Recommendation**

- One paragraph stating the recommended value for this determinant together with timing, explanation of any notations, and any advice to user regarding interpretation of the results.
- For a urinary determinant, a comment may be needed on the use of creatinine or specific gravity for sample screening or correction.
- Add a final sentence giving the recommended BEI<sup>®</sup> in SI equivalent units.
- For those determinants with an Nq notation, some guidance values for the occupational health professional as an aid to interpretation of results.

*[End of Section on First Determinant]*

**SECOND DETERMINANT, IF ANY  
(e.g., FORMIC ACID IN URINE)**

**ANALYTICAL METHODS**

- Provide acceptable method(s) with citation(s), e.g., headspace gas chromatography with a flame ionization detector (FID).high-pressure liquid chromatographic (HPLC) method with ultraviolet detection.
- Describe why a currently accepted method would be unacceptable, if data exist.

**Sampling and Storage**

(headings as in first section . . .)

*[End of Section on Second Determinant]*

**Other Reference Values**

Short description of other organizations/jurisdictions index/indices using the same determinant(s) as the BEI(s)<sup>®</sup>. Provide basis/bases, if known.

**Other Indicators of Exposure**

Include here any other proposed determinants that are not recommended as BEI<sup>®</sup> due to insufficient

data, etc. Include brief descriptions of studies and summary of why the determinant was not considered acceptable by the Committee.)

## BEI® Chronology

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

## References

- List citations in alphabetical order by author, rather than in the order cited in the text.
- Use author, date for citation in the text, rather than citation number.
- Unlike the reference style of the past, use a modified MedLine style, all extraneous punctuation and capitalization are eliminated in journal citations (e.g., article titles are treated as a sentence).
- Avoid personal communications.
- Use of unpublished information requires that the entire study or communication be on file at ACGIH® headquarters and that full disclosure must be transferred to ACGIH® so the Committee may cite these data as necessary and also make the information available for public release, if requested.
- Samples appear in Appendix F.

<b>BEI® Chronology: Cadmium</b>					
<b>Date</b>	<b>Action</b>	<b>Determinant</b>	<b>Sampling Time</b>	<b>BEI®</b>	<b>Notation</b>
1986	Proposed	Cadmium in urine	Not critical	10 µg/g creatinine	†
		Cadmium in blood	Not critical	10 µg/L	†
1987	Proposed	Cadmium in urine	Not critical	10 µg/g creatinine	B
		Cadmium in blood	Not critical	10 µg/L	B
1988	Adopted	Cadmium in urine	Not critical	10 µg/g creatinine	B
		Cadmium in blood	Not critical	10 µg/L	B
1991	Proposed	Cadmium in urine	Not critical	5 µg/g creatinine	B
		Cadmium in blood	Not critical	5 µg/L	B

## Appendix F: Reference Samples

## REFERENCE SAMPLES

### Journal Articles

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

Monster AC; Boersma G: Simultaneous determination of trichloroethylene and metabolites in blood and exhaled air by gas chromatography. Arch Occup Environ Health 35:155–163 (1975).

Ogata M; Takatsuka Y; Tomokuni K: A simple method for the quantitative analysis of urinary trichloroethanol and trichloroacetic acid as an index of trichloroethylene exposure. Br J Ind Med 27:378–381 (1970).

Triebig G; Trautner P; Weltle D; et al.: Investigations on neurotoxicity of chemical substances at the workplace. III. Determination of the motor and sensory nerve conduction velocity in persons occupationally exposed to trichloroethylene. Int Arch Occup Environ Health 51:25–34 (in German) (1982).

### Online Citations

*NOTE:* Print or download section(s) used and include with other references sent to the ACGIH® office.

U.S. National Library of Medicine: **Substance name**. In: Hazardous Substances Data Bank. Toxicology Data Network (TOXNET). Online at: <http://toxnet.nlm.nih.gov/> [print or download section(s) used and include with other references sent to the ACGIH® office.]

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> [print or download section(s) used and include with other references sent to the ACGIH® office.]

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](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).

U.S. National Cancer Institute: Carcinogenesis Bioassay of Trichloroethylene, CAS No.79-02-6. National Cancer Institute Technical Report Series No. 2. DHEW (NIH) Pub. No. 76-802. NCI, Bethesda, MD (1976).

## 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)

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## **Appendix G: Symposia and Workshops**

## Procedure for Developing a Symposium or Workshop

The education of BEI<sup>®</sup> Committee members is an important aspect of the development of BEIs<sup>®</sup> and BEI<sup>®</sup> *Documentation*. Suggestions for educational symposium topics should be forwarded to the ACGIH<sup>®</sup> Education Development Manager in writing. Symposium topics can come from Committee members, ACGIH<sup>®</sup> Staff, and external parties. The proposal should include a justification for the necessity of the symposium, the topic's relevance to the BEI<sup>®</sup> Committee, a suggested list of participants, and if possible, a list of potential academic, governmental, or industrial sponsors.

Several criteria will be used to determine the appropriateness of the symposium as being of interest to the BEI<sup>®</sup> Committee. A symposium must be the most efficient format in which to present BEI<sup>®</sup> Committee members with new information that will assist in the scientific judgment used in the setting of BEIs<sup>®</sup> and in the writing of supporting *Documentation*.

Because of the timing of BEI<sup>®</sup> 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 ongoing research, scientific uncertainty about currently available data, or another scientific reason for the symposium. The Committee will focus its review on how well a symposium adds to the scientific understanding and decision-making of the BEI<sup>®</sup> Committee.

Representatives of external organizations may have expressed a desire to meet with the BEI<sup>®</sup> 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 BEI<sup>®</sup> 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 Committee will review the proposal (see Symposium Proposal Form) in a timely fashion and rate its relevance to the ongoing BEI<sup>®</sup> process. The Committee may seek additional input from members of the BEI<sup>®</sup> Committee or other experts, as necessary, during its review. The timetable for proposing and approving symposia is in the next section.

The Steering Subcommittee will make a final recommendation to the Education Development Manager, indicating whether the BEI<sup>®</sup> 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 BEI<sup>®</sup> Committee is accepted by the Education Development Manager, the BEI<sup>®</sup> Steering Subcommittee will identify a small "task force" to work with ACGIH<sup>®</sup> Staff during the development phase. It is recommended that a member of the Steering Subcommittee serve as a member. The task force will work closely with the Education Development Manager and will seek input and ideas from BEI<sup>®</sup> Committee members about sponsors, speakers, format, etc. The task force will be responsible for ensuring that the BEI<sup>®</sup> 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 Development Manager will be informed of the proposal and the Committee's review. The individual who submitted the proposal will also be notified. The Education Development Manager may decide to proceed without the BEI<sup>®</sup> Committee's formal sponsorship or involvement. In this latter case, potential symposium sponsors and attendees must be made aware that the BEI<sup>®</sup> Committee has expressed no interest in formal sponsorship or participation. In addition, it must be made clear that BEI<sup>®</sup> Committee members will not attend the meeting in their capacity as members or representatives of the BEI<sup>®</sup> Committee, although they may, of course, attend as interested scientists.

## **Symposium Timetable**

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

## **Symposium Proposal Form**

1. Purpose of symposium – statement delineating what is of interest to BEI<sup>®</sup> deliberations and why
  - 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.
  - Presentation of new information that facilitates setting of BEI<sup>®</sup> using best available data and scientific judgment
2. Description of expected participants
3. List of potential sponsors

## **Appendix H: ACGIH Education Development Planner**

**ACGIH<sup>®</sup>**  
**Event Development Planner (E.D.P.)**

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Instructions for completion: This is a comprehensive form designed to assist both ACGIH<sup>®</sup> Committee members and staff in the planning of workshops, courses, conferences and symposia. Since this is a working document, not all questions can be fully answered from the outset. However, please complete all pertinent items to the best of your ability. Please obtain the necessary signatures before submitting to ACGIH<sup>®</sup> staff. For assistance at any time in filling out this worksheet or for any other questions about educational events, please contact Ryan Peltier, Science and Education Manager at 513-742-6176 or [rpeltier@acgih.org](mailto:rpeltier@acgih.org).

**IMPORTANT NOTES:**

- Symposia and conference dates must be one year from submittal for domestic events and eighteen months from submittal for international events unless prior arrangements have been made.
- Please be detailed when answering questions. Please make sure all items marked with an asterisk are completed before the initial submittal.

Original Date of Submittal: \_\_\_\_\_

Revision Date: \_\_\_\_\_

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**PLEASE TYPE DIRECTLY IN THE FIELD BELOW THE PROMPT**

\*Items must be completed before submittal to ACGIH<sup>®</sup>

## **1. EDUCATIONAL SCOPE OF EVENT**

\*Type of Event:

- Symposium – A symposium is a focused meeting on a subject of current or continuing interest. A symposium's principal purpose is to bring expert authors on a given subject together to share their knowledge and expertise with an audience.
- Conference – A conference consists of programming where multiple speakers present papers and/or presentations on different topics relating to a theme, material, process, or industry. Conferences typically have concurrent sessions.
- Workshop – Workshops are 1–5 day programs devoted to one subject and are usually led by 1–3 instructors that are considered leaders in their field.
- Course – A course is similar to a workshop in length and scope, however, a course typically culminates in a measured exam for certification purposes.
- Distance Education – Distance education refers to any online education program including webinars and online courses.

\*Description of Event:

\*Goals of Event (List educational goals):

\*Deliverables (What will be the contribution to the science?):

\*List the Committee supporting this educational event:

\*Signature of Committee Chair (Signature indicates that the Committee supports the science behind the proposed educational event) >

\*Chair - Sign and Date:

\*Name of Person Submitting E.D.P. –

## **2. AUDIENCE**

The determination of potential audience is a paramount step to a successful event for ACGIH®. Please keep the following items in mind when answering the questions below:

- For a symposium or conference that will utilize a hotel or conference center, a minimum of 125 paid attendees is necessary.
- For a course or workshop that will utilize a hotel or conference center, a minimum of 30 attendees is necessary.

\*List projected attendance (please include a minimum and maximum):

\*Give a detailed description of the potential audience:

\*List industries that will be interested in this event:

\*List other associations or organizations that may have an interest in this event:

\*What continuing education should be offered?

## **3. LOGISTICS**

\*What type of venue is needed for this event?  Hotel  ACGIH<sup>U</sup> Room  Convention Center

\*Why is this type of venue needed?

\*Are there any special accommodations we need to be aware of?

1. **\*What is the first choice of geographic location and why?**
  
2. **\*What is the second choice of geographic location and why?**
  
3. **\*When should this event be offered? Year:**
  
4. Spring Summer Fall Winter
  
5. **\*How many days will the event last?**
  
6. **\*Will there be any pre- or post-event activities?**
  
7. **\*List name and date of any other events you are aware of that may impact this event:**
  
8. **\*List names and dates of any similar events that have been held in the past:**

## **EVENT FORMAT – SYMPOSIUM OR CONFERENCE**

**COMPLETE THIS SECTION ONLY IF PLANNING A SYMPOSIUM OR CONFERENCE**

1. Will there be a keynote speaker/s? YES NO
2. If yes, how many?
3. List names of potential keynote speakers:
4. List the number of general or plenary sessions per day:
5. Will the event have concurrent sessions? YES NO
6. If yes, list the number of concurrent sessions needed each day:
7. If yes, list the number of speakers needed for each concurrent session:
8. Will the event have roundtables or panel discussions? YES NO
9. If yes, list the number needed per day:
10. Will there be any pre- or post-event activities?
11. List the number of moderators needed per day:

12. **ACGIH<sup>U</sup> strongly encourages a “call for papers” for all conferences and symposia. If you do not plan on having a “call for papers” please explain:**
13. **List outlets where the call for papers should be advertised:**
14. **Will there be a poster session? YES NO**
15. **Is there a desire to print an abstract book? YES NO**
16. **Is there a desire to have a published proceeding? YES NO**
17. **If yes, list possible journals for the proceedings publication:**

**\*ACGIH<sup>U</sup> cannot guarantee publication in JOEH.**

## **EVENT FORMAT – COURSE OR WORKSHOP**

**COMPLETE THIS SECTION ONLY IF PLANNING A COURSE OR WORKSHOP**

1. **List the desired number of instructors:**
2. **List the name/s of potential instructors:**
3. **Will there be a demonstration section of the event? YES NO**
4. **If yes, is there any special equipment or software needed?**
5. **Will there be a hands-on portion of the event? YES NO**
6. **If yes, is there any special equipment or software needed?**
7. **Are there any books, manuals or other text needed?**

**EVENT FORMAT – DISTANCE EDUCATION**  
**COMPLETE THIS SECTION ONLY IF PLANNING AN ONLINE PROGRAM**

1. List the desired number of speakers?
2. List name/s of potential speakers?
3. Indicate whether speakers have previously presented in an online format:
4. Online courses and webinars typically have testing requirements to receive CM points. Who will develop the test?

**FINANCIAL**

1. Are there any other associations or organizations that might be willing to co-sponsor the event?
2. Are there any associations or organizations that might be willing to sponsor a welcome reception or meal?
3. List possible sources of additional funding (include contact names):
4. Projected number of individuals, if any, who will receive complimentary registrations (List by category):  Speakers \_\_\_\_  Task Force \_\_\_\_  Committee \_\_\_\_  Other \_\_\_\_
5. Projected number of individuals who will receive travel support. Please specify the type and extent of support offered:
6. List any extraordinary expenses anticipated (i.e., international travel support, honorarium, etc.):

## **TASK FORCE**

1. **List the number of persons required on Technical Program Task Force (list).**
2. **List the suggested ACGIH<sup>U</sup> Committee Members for Technical Program Task Force (list).**
3. **List the names of other experts for the Technical Program Task Force. Please list area of expertise and organization name.**
4. **What is the expected number of meetings and conference calls needed to develop the event? In person meetings: \_\_\_\_\_ Conference Calls: \_\_\_\_\_**
5. **For in person meetings, where should they be held?**

## **MARKETING**

1. **List industry trade publications where this event might be advertised:**
2. **List any listservs that you are aware of that might be potential avenues of advertising:**
3. **List organizations that might be willing to share their member lists:**