

2020

TLVs[®] and BEIs[®]

Based on the Documentation of the

Threshold Limit Values

for Chemical Substances
and Physical Agents

&

Biological Exposure Indices



Signature Publications

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POLICY STATEMENT ON THE USES OF TLVs® AND BEIs®

The Threshold Limit Values (TLVs®) and Biological Exposure Indices (BEIs®) are developed as guidelines to assist in the control of health hazards. These recommendations or guidelines are intended for use in the practice of industrial hygiene, to be interpreted and applied only by a person trained in this discipline. They are not developed for use as legal standards and ACGIH® does not advocate their use as such. However, it is recognized that in certain circumstances individuals or organizations may wish to make use of these recommendations or guidelines as a supplement to their occupational safety and health program. ACGIH® will not oppose their use in this manner, if the use of TLVs® and BEIs® in these instances will contribute to the overall improvement in worker protection. However, the user must recognize the constraints and limitations subject to their proper use and bear the responsibility for such use.

The Introductions to the TLV®/BEI® Book and the TLV®/BEI® *Documentation* provide the philosophical and practical bases for the uses and limitations of the TLVs® and BEIs®. To extend those uses of the TLVs® and BEIs® to include other applications, such as use without the judgment of an industrial hygienist, application to a different population, development of new exposure/recovery time models, or new effect endpoints, stretches the reliability and even viability of the database for the TLV® or BEI® as evidenced by the individual *Documentation*.

It is not appropriate for individuals or organizations to impose on the TLVs® or the BEIs® their concepts of what the TLVs® or BEIs® should be or how they should be applied or to transfer regulatory standards requirements to the TLVs® or BEIs®.

Approved by the ACGIH® Board of Directors on March 1, 1988.

Special Note to User

The values listed in this book are intended for use in the practice of industrial hygiene as guidelines or recommendations to assist in the control of potential workplace health hazards and for no other use. These values are *not* fine lines between safe and dangerous concentrations and *should not* be used by anyone untrained in the discipline of industrial hygiene. **It is imperative that the user of this book read the Introduction to each section and be familiar with the *Documentation* of the TLVs® and BEIs® before applying the recommendations contained herein.** ACGIH® disclaims liability with respect to the use of the TLVs® and BEIs®.

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ACGIH® is a 501(c)(3) charitable scientific organization that advances occupational and environmental health. The organization has contributed substantially to the development and improvement of worker health protection. The organization is a professional society, not a government agency.

The *Documentation of the Threshold Limit Values and Biological Exposure Indices* is the source publication for the TLVs® and BEIs® issued by ACGIH®. That publication gives the pertinent scientific information and data with reference to literature sources that were used to base each TLV® or BEI®. For better understanding of the TLVs® and BEIs®, it is essential that the *Documentation* be consulted when the TLVs® or BEIs® are being used. For further information, contact The Science Group, ACGIH®. The most up-to-date list of substances and agents under study by the committees is available at acgih.org/tlv-bei-guidelines/documentation-publications-and-data/under-study-list.

Comments, suggestions, and requests for interpretations or technical information should be directed to The Science Group at the address below or to the following e-mail address: science@acgih.org. To place an order, visit our website at acgih.org/store, contact Customer Service at the address or phone number below, or use the following e-mail address: customerservice@acgih.org.

***Help ensure the continued development of
TLVs® and BEIs®. Make a tax deductible donation to
the FOHS Sustainable TLV®/BEI® Fund today!***

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In the event significant errata are required, they will be listed on the ACGIH® website at acgih.org/tlv-bei-guidelines/policies-procedures-presentations.

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STATEMENT OF POSITION REGARDING THE TLVs® AND BEIs®

The American Conference of Governmental Industrial Hygienists (ACGIH®) is a private, not-for-profit, nongovernmental corporation whose members are industrial hygienists or other occupational health and safety professionals dedicated to promoting health and safety within the workplace. ACGIH® is a scientific association. ACGIH® is not a standards-setting body. As a scientific organization, it has established committees that review the existing published, peer-reviewed scientific literature. ACGIH® publishes guidelines known as Threshold Limit Values (TLVs®) and Biological Exposure Indices (BEIs®) for use by industrial hygienists in making decisions regarding safe levels of exposure to various chemical and physical agents found in the workplace. In using these guidelines, industrial hygienists are cautioned that the TLVs® and BEIs® are only one of multiple factors to be considered in evaluating specific workplace situations and conditions.

Each year, ACGIH® publishes its TLVs® and BEIs® in a book. In the introduction to the book, ACGIH® states that the TLVs® and BEIs® are guidelines to be used by professionals trained in the practice of industrial hygiene. The TLVs® and BEIs® are not designed to be used as standards. Nevertheless, ACGIH® is aware that in certain instances the TLVs® and the BEIs® are used as standards by national, state, or local governments.

Governmental bodies establish public health standards based on statutory and legal frameworks that include definitions and criteria concerning the approach to be used in assessing and managing risk. In most instances, governmental bodies that set workplace health and safety standards are required to evaluate health effects, economic and technical feasibility, and the availability of acceptable methods to determine compliance.

ACGIH® TLVs® and BEIs® are not consensus standards. Voluntary consensus standards are developed or adopted by voluntary consensus standards bodies. The consensus standards process involves canvassing the opinions, views, and positions of all interested parties and then developing a consensus position that is acceptable to these parties. While the process used to develop a TLV® or BEI® includes public notice and requests for all available and relevant scientific data, the TLV® or BEI® does not represent a consensus position that addresses all issues raised by all interested parties (e.g., issues of technical or economic feasibility). The TLVs® and BEIs® represent a scientific opinion based on a review of existing peer-reviewed scientific literature by committees of experts in public health and related sciences.

ACGIH® TLVs® and BEIs® are health-based values. ACGIH® TLVs® and BEIs® are established by committees that review existing published and peer-reviewed literature in various scientific disciplines (e.g., industrial hygiene, toxicology, occupational medicine, and epidemiology). Based on the available information, ACGIH® formulates a conclusion on the level of exposure that the typical worker can experience without adverse health effects. The TLVs® and BEIs® represent conditions under which ACGIH® believes that nearly all workers may be repeatedly exposed without adverse health effects. They are not

fine lines between safe and dangerous exposures, nor are they a relative index of toxicology. The TLVs[®] and BEIs[®] are not quantitative estimates of risk at different exposure levels or by different routes of exposure.

Since ACGIH[®] TLVs[®] and BEIs[®] are based solely on health factors, there is no consideration given to economic or technical feasibility. Regulatory agencies should not assume that it is economically or technically feasible for an industry or employer to meet TLVs[®] or BEIs[®]. Similarly, although there are usually valid methods to measure workplace exposures at the TLVs[®] and BEIs[®], there can be instances where such reliable test methods have not yet been validated. Obviously, such a situation can create major enforcement difficulties if a TLV[®] or BEI[®] was adopted as a standard.

ACGIH[®] does not believe that TLVs[®] and BEIs[®] should be adopted as standards without full compliance with applicable regulatory procedures, including an analysis of other factors necessary to make appropriate risk management decisions. However, ACGIH[®] does believe that regulatory bodies should consider TLVs[®] or BEIs[®] as valuable input into the risk characterization process (hazard identification, dose-response relationships, and exposure assessment). Regulatory bodies should view TLVs[®] and BEIs[®] as an expression of scientific opinion.

ACGIH[®] is proud of the scientists and the many members who volunteer their time to work on the TLV[®] and BEI[®] Committees. These experts develop written *Documentation* that includes an expression of scientific opinion and a description of the basis, rationale, and limitations of the conclusions reached by ACGIH[®]. The *Documentation* provides a comprehensive list and analysis of all the major published peer-reviewed studies that ACGIH[®] relied upon in formulating its scientific opinion. Regulatory agencies dealing with hazards addressed by a TLV[®] or BEI[®] should obtain a copy of the full written *Documentation* for the TLV[®] or BEI[®]. Any use of a TLV[®] or BEI[®] in a regulatory context should include a careful evaluation of the information in the written *Documentation* and consideration of all other factors as required by the statutes which govern the regulatory process of the governmental body involved.

- ACGIH® is a not-for-profit scientific association.
- ACGIH® proposes guidelines known as TLVs® and BEIs® for use by industrial hygienists in making decisions regarding safe levels of exposure to various hazards found in the workplace.
- ACGIH® is not a standard-setting body.
- Regulatory bodies should view TLVs® and BEIs® as an expression of scientific opinion.
- TLVs® and BEIs® are not consensus standards.
- ACGIH® TLVs® and BEIs® are based solely on health factors; there is no consideration given to economic or technical feasibility. Regulatory agencies should not assume that it is economically or technically feasible to meet established TLVs® or BEIs®.
- ACGIH® believes that TLVs® and BEIs® should NOT be adopted as standards without an analysis of other factors necessary to make appropriate risk management decisions.
- TLVs® and BEIs® can provide valuable input into the risk characterization process. Regulatory agencies dealing with hazards addressed by a TLV® or BEI® should review the full written Documentation for the numerical TLV® or BEI®.

ACGIH® is publishing this Statement in order to assist ACGIH® members, government regulators, and industry groups in understanding the basis and limitations of the TLVs® and BEIs® when used in a regulatory context. This Statement was adopted by the ACGIH® Board of Directors on March 1, 2002.

TLV®/BEI® DEVELOPMENT PROCESS: AN OVERVIEW

Provided below is an overview of the ACGIH® TLV®/BEI® Development Process. Additional information is available on the ACGIH® website (acgih.org). Please also refer to the attached Process Flowchart (Figure 1).

1. **Under Study:** When a substance or agent is selected for the development or revision of a TLV® or BEI®, the appropriate committee places it on its Under Study list. Each committee determines its own selection of chemical substances or physical agents for its Under Study list. A variety of factors is used in this selection process, including prevalence, use, number of workers exposed, availability of scientific data, existence/absence of a TLV® or BEI®, age of TLV® or BEI®, input from the public, etc. The public may offer input to any TLV® or BEI® Committee by e-mail to science@acgih.org.

The Under Study lists serve as notification and invitation to interested parties to submit substantive data and comments to assist the committees in their deliberations. Each committee considers only those comments and data that address issues of health and exposure, but not economic or technical feasibility. Comments must be accompanied by copies of substantiating data, preferably in the form of peer-reviewed literature. Should the data be from unpublished studies, ACGIH® requires written authorization from the owner of the studies granting ACGIH® permission to (1) use, (2) cite within the *Documentation*, and (3) upon request from a third party, release the information. All three permissions must be stated/covered in the written authorization. (See endnote for a sample permission statement.) Electronic submission of all information to the ACGIH® Science Group at science@acgih.org is preferred and greatly increases the ease and efficiency with which the committee can consider the comments or data.

The Under Study list is published each year by February 1 on the ACGIH® website (acgih.org/tlv-bei-guidelines/documentation-publications-and-data/under-study-list), in the *Annual Reports of the Committees on TLVs® and BEIs®*, and later in the annual *TLVs® and BEIs®* book. In addition, the Under Study list is updated by July 31 into a two-tier list.

- Tier 1 entries indicate which chemical substances and physical agents **may** move forward as an NIC or NIE in the upcoming year, based on their status in the development process.
- Tier 2 consists of those chemical substances and physical agents that **will not** move forward, but will either remain on, or be removed from, the Under Study list for the next year.

This updated list will remain in two-tiers for the balance of the year. All updates to the Under Study lists and publication of the two-tier lists are posted on the ACGIH® website (acgih.org/tlv-bei-guidelines/documentation-publications-and-data/under-study-list).

2. **Draft Documentation:** One or more members of the appropriate committee are assigned the task of collecting information and data from the scientific literature, reviewing results of unpublished studies submitted for review,

and developing a draft TLV[®] or BEI[®] *Documentation*. The draft *Documentation* is a critical evaluation of the scientific literature relevant to recommending a TLV[®] or BEI[®]; however, it is not an exhaustive critical review of all studies but only those pertinent to identifying the critical effect and setting the TLV[®]. Particular emphasis is given to papers that address minimal or no adverse health effect levels in exposed animals or workers that deal with the reversibility of such effects, or in the case of a BEI[®], that assess chemical uptake and provide applicable determinant(s) as an index of uptake. Human data, when available, are given special emphasis. This draft *Documentation*, with its proposed TLV[®] or BEI[®], is then reviewed and critiqued by additional committee members, and eventually by the full committee. This often results in several revisions to the draft *Documentation* before the full committee accepts the proposed draft TLV[®] or BEI[®] and draft *Documentation*. The draft *Documentation* is not available to the public during this stage of the development process and is not released until it is at the Notice of Intended Changes (NIC) stage. Authorship of the *Documentation* is not disclosed.

3. Notice of Intended Changes (NIC):

[Notice of Intent to Establish (NIE): *The Physical Agents section of the TLVs[®] and BEIs[®] book also uses the term Notice of Intent to Establish (NIE) in addition to NIC. An NIE follows the same development process as an NIC. For purposes of this process overview, only the term NIC is used.]*

When the full committee accepts the draft *Documentation* and its proposed TLV[®] or BEI[®], the *Documentation* and proposed values are then recommended to the ACGIH[®] Board of Directors for ratification as an NIC. If ratified, each proposed TLV[®] or BEI[®] is published as an NIC in the *Annual Reports of the Committees on TLVs[®] and BEIs[®]*, which is published in the ACGIH[®] newsletter, and is also available online for purchase at acgih.org/store. At the same time, the draft *Documentation* is made available through ACGIH[®] Customer Service or online at www.acgih.org/store. All information contained in the *Annual Reports of the Committees on TLVs[®] and BEIs[®]* is integrated into the annual *TLVs[®] and BEIs[®]* book, which is usually available to the general public in February or March of each year. Following the NIC ratification by the ACGIH[®] Board of Directors, interested parties, including ACGIH[®] members, are invited to provide data and substantive comments, preferably in the form of peer-reviewed literature, on the proposed TLVs[®] or BEIs[®] contained in the NIC. Should the data be from unpublished studies, ACGIH[®] requires written authorization from the owner of the studies granting ACGIH[®] permission to (1) use, (2) cite within the *Documentation*, and (3) upon request from a third party, release the information. All three permissions must be stated/covered in the written authorization. (See endnote for a sample permission statement.) The most effective and helpful comments are those that address specific points within the draft *Documentation*. Changes or updates are made to the draft *Documentation* as necessary. If the committee finds or receives substantive data that