



Designation: E2565 – 21

Standard Guide for Consensus-Based Process for an Occupational Safety and Health Standard That Includes an Occupational Exposure Guideline¹

This standard is issued under the fixed designation E2565; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope*

1.1 This guide presents a framework for a stakeholder-focused, consensus-based decision-making process for occupational safety and health standard development activities that include adoption or development of occupational exposure guidelines (OEGs) as a part of occupational health and safety standards.

1.2 This guide applies to safety and health standard development activities in which an occupational exposure guideline will be included as one element of a comprehensive standard that addresses safety and health management strategies such as communication, monitoring, and controls. It is not meant to be used to develop an OEG apart from the context of such management strategies. In cases where other occupational exposure limit (OEL) establishing bodies have developed OELs, those may be reviewed, assimilated, or adapted rather than recreated *ab initio*.

1.3 This guide does not replace existing consensus-based decision-making or committee participation processes that are used to develop safety and health standards. It is intended to be used in conjunction with such processes to improve scientific and technical input and stakeholder involvement in occupational safety and health decision-making for such standards.

1.4 *Limitations*—This guide does not prescribe specific methods for generating or evaluating scientific and technical data related to assessing a particular occupational safety and health issue. Occupational safety and health standards apply to a wide variety of substances and occupational exposure circumstances. It is not possible to anticipate all situations where an OEG may be useful for a standard. This guide will be helpful in promoting appropriate balance and input, but the consensus process must deal with real-world complexities that individual standards may involve.

¹ This guide is under the jurisdiction of ASTM Committee E34 on Occupational Health and Safety and is the direct responsibility of Subcommittee E34.80 on Industrial Health.

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1.5 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards*:²

E1542 [Terminology Relating to Occupational Health and Safety](#)

3. Terminology

3.1 *Definitions*—For definitions of terms used in this standard, see Terminology E1542.

3.2 *Definitions*:

3.2.1 *informed decision, n*—agreement reached by affected stakeholders, which is obtained by a process by which affected stakeholders (1) are involved in a participative process that creates common understanding of the issues, concerns, and priorities held by all affected stakeholders; (2) assess, prioritize, and select actions to improve the problem situation; and (3) achieve consensus on specific initiatives related to the consensus-based standard development process.

3.2.2 *occupational exposure guideline (OEG), n*—a guideline used in an ASTM standard for limiting exposure to a chemical, physical, or biological agent to prevent unacceptable risk of harm to worker populations. OEGs may be established for mixtures.

3.2.2.1 *Discussion*—An OEG may take one or more of several forms and should include considerations of the averaging time (for example, ceiling, short term limits, full shift limits, etc.) and the target (individual workers, process or activity, population, position, etc.).

3.2.3 *occupational exposure limit (OEL), n*—generic term limiting exposure to a chemical, physical, or biological agent.

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

*A Summary of Changes section appears at the end of this standard

3.2.4 *stakeholder (interested party)*, *n*—person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity.

3.3 Abbreviations:

3.3.1 *CBSD*—consensus-based occupational safety and health standard development

4. Summary of Guide

4.1 The consensus-based occupational safety and health standard development (CBSD) process is established to identify affected stakeholders, facilitate relevant scientific and technical input, and provide appropriate balance with the goal of optimizing decision-making with respect to occupational safety and health standards that include an OEG.

4.2 The CBSD process facilitates informed decision-making among affected committee and subcommittee members with consensus developed through ASTM's review and ballot procedures. This guide promotes stakeholder involvement and technical input, but does not specify precise deliberation details or decision criteria.

5. Significance and Use

5.1 This guide is designed to help identify and integrate affected stakeholder interests and to include relevant scientific and technical information when developing occupational safety and health standards that include or are proposed to include an OEG.

5.2 This guide shall be used when updating an occupational safety and health standard containing an OEG.

5.3 While use of the CBSD process is required for occupational safety and health standards that include an OEG, it may also be used to improve stakeholder involvement and technical input for other occupational safety and health standards.

5.4 The CBSD process is intended:

(1) To obtain representation on the committee or subcommittee from sectors that are substantially impacted by a specific standard project; and

(2) To obtain adequate input when the project requires review and analysis of information that is highly technical, very specialized, or not widely available.

6. Consensus-Based Occupational Safety and Health Standard Development Process

6.1 *Identification of Affected Stakeholders and Determination of Committee Balance:*

6.1.1 At the beginning of a standards project, prior to its approval, membership in the relevant committee or subcommittee shall be classified according to interest and reviewed for balance with respect to the issues and impacts related to the particular standard activity.

6.1.2 Affected stakeholders shall be identified for the particular standard activity.

6.1.3 If all affected stakeholder groups are not represented, under-represented, or if representation is such that an informed decision cannot be achieved, the committee or subcommittee

shall actively recruit members from the unrepresented or under-represented affected stakeholder groups and shall document such outreach efforts. Recruiting may include contacting potential individuals, companies, organizations, trade groups, unions, or professional associations identified as representing the appropriate interest to notify them of the standards activity and invite them to become part of the standard development process. The hallmarks of the consensus process are openness, shared understanding, willingness to achieve consensus, and rigorous democratic procedures.

6.2 *Scientific and Technical Input:*

6.2.1 At the beginning of an occupational safety and health standards project that includes an OEG, prior to the project approval, the committee or subcommittee shall identify scientific and technical issues and information relevant to the standards development process. A general request for submission of relevant scientific and technical information will be made to the Society.

6.2.2 The committee or subcommittee shall evaluate its membership to determine if additional critical information, resources, or expertise outside its membership is needed to complete development of an appropriate standard. If necessary, a general request for additional scientific and technical input and participation shall be made.

6.2.3 Additional scientific and technical input may be obtained in one or more of the following ways:

(1) Experts may be recruited to the committee or subcommittee as members; or

(2) Experts may be invited to participate in committee or subcommittee activities as advisors or correspondents; or

(3) Information may be developed through independent meetings or scientific symposia where experts are invited to present current assessments of the scientific or technical issues of interest.

6.2.3.1 The committee shall communicate its activities through liaison with scientific, professional, governmental, and non-governmental organizations with potential interest in the standard project or in the OEG element of the standard project. Input and concerns of such organizations shall be considered by the committee, including whether to proceed with the standard project.

6.2.4 Outreach efforts and requests for additional scientific and technical information shall be documented.

7. Process for Developing an Occupational Exposure Guideline (OEG)

7.1 *Initial Determinations:*

7.1.1 The standard developing committee shall determine if the safety and health standard needs an OEG because, among other reasons, the standard will contain provisions, such as for monitoring or medical surveillance, which are triggered by an OEG.

7.1.2 The committee shall review established OELs, including those from regulatory agencies, professional organizations, international standards, and manufacturers' recommendations to determine whether an existing limit is appropriate for the purposes of the standard under development.