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Standard Guide for Consensus-based Process for an Occupational Safety and Health Standard that Includes an Occupational Exposure Guideline[1]

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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.

2. Terminology

2.1 *Definitions*—Except as modified below this guide will utilize the definitions in *Regulations Governing ASTM Technical Committees*.

2.2 *Definitions:*

2.2.1 *stakeholder, n*—any individual, group, company, organization, government, or other entity, which may be directly affected by or has a stake in the outcome of the specific consensus-based standard development process.

2.2.2 *consensus-based occupational safety and health standard development (CBSD) process, n*—a process to provide appropriate balance, scientific and technical information and stakeholder involvement for occupational safety and health standards which include or are proposed to include an occupational exposure guideline.

2.2.3 *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.

2.2.4 *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.

2.2.4.1 *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.).

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

3. Summary of Guide

3.1 The consensus-based occupational safety and health standard development (CBSD) process is established to identify affected stakeholders, facilitate relevant scientific and

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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.

3.2 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.

4. Significance and Use

4.1 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.

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

4.3 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.

4.4 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.

5. Consensus-based Occupational Safety and Health Standard Development Process

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

5.1.1 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.

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

5.1.3 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.

5.2 *Scientific and Technical Input:*

5.2.1 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.

5.2.2 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.

5.2.3 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.

5.2.3.1 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.

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

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

6.1 *Initial Determinations*

6.1.1 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.

6.1.2 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.

6.2 *Health Considerations*

6.2.1 When establishing a new OEG or endorsing an existing OEL, protection of worker health shall be the primary consideration.

6.3 *Application of OEG*

6.3.1 If an OEG is deemed appropriate for an existing or new occupational health and safety standard, the committee shall define how the OEG is to be applied. The following aspects may be considered:

6.3.1.1 The route of exposure. For example, consider inhalation, dermal, ingestion, or a combination of these routes of exposure.

6.3.1.2 Limitations of an OEG, recognizing that an OEG is generally not a fine line between safe and unsafe levels.

6.3.1.3 The type of OEG that is to be recommended. For example, consider whether the OEG should be a time-weighted average, a ceiling limit, a short-term exposure limit, or an exposure immediately dangerous to life and health, or combinations thereof. If more than one type of OEG is appropriate include all those that apply.

6.3.1.4 If the occupational exposure contains multiple substances, consider the impact of mixed exposures.

6.3.1.5 Time pattern of exposures and potential health effects including adjustments for excursions and non-traditional shifts.

6.3.1.6 Sensitive populations.

6.3.1.7 Characteristics of exposure. For example, if inhalation is a route of exposure, consider aerosol size; if a physical hazard is considered frequency or wavelength may be important.

6.3.1.8 Where the exposure is defined; for example where is the breathing zone when various types of personal protective equipment (PPE) are used.

6.4 *Measurement Considerations*

6.4.1 The method of measuring the contaminant or agent of interest shall be considered in the development of a standard that includes an OEG. The limit of detection, the limit of quantification and the expected variation must be considered as they relate to determining workplace compliance with the OEG.

6.4.2 Analytical approaches can include alternative measurement techniques such as the use of a surrogate for a mixture, the use of direct-reading instruments, or other representative techniques.

6.4.3 Practical considerations of the analytical method should consider the applicability of the method for performing source, area, and personal sampling. The cost of the analytical method should also be considered in specifying alternative measurement strategies.

6.4.4 The effect of variability in results between different sampling and analytical strategies should be considered.

7. Feasibility

7.1 While an OEG should be based primarily on health considerations, feasibility is an important consideration in the development of an overall usable standard. Feasibility is a key consideration of the *standard as a whole*, but not necessarily of the OEG.

7.2 Technical and economic feasibility considerations may take several forms:

7.2.1 In determining the form of an OEG, for example, when a surrogate would be appropriate in light of the reliability of the available methods of measurement at the exposure levels of interest.

7.2.2 In determining the control measures to be employed in conforming with an OEG.

7.2.3 In determining the level of an OEG in certain circumstances where the OEG generated by a purely health-based assessment would be impractical, for example, the OEG would be below the ambient exposure level.

7.3 It shall be the responsibility of the committee or subcommittee writing the standard to determine how feasibility considerations will be factored into the standard.

8. Keywords

8.1 consensus based standard development; occupational exposure guideline; occupational exposure limit; OEG; OEL; PEL; permissible exposure limit; stakeholder