OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEMS:

Processes for Development of National and International Voluntary Consensus Standards

FINAL REPORT

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Disclaimer

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List of Abbreviations and Acronyms

AHG	Ad hoc group
AIHA	American Industrial Hygiene Association
ANS	American National Standard
ANSI	American National Standards Institute
ASD	Accredited Standards Developer
ASME	American Society of Mechanical Engineers
ASSE	American Society of Safety Engineers
ASSP	American Society of Safety Professionals
ASTM	American Society for Testing and Materials
BS	British Standard
BSI	British Standards Institute
BSR	Board of Standards Review
CD	Committee Draft
CS	Central Secretariat
DIS	Draft International Standard
EIA	Electronic Industries Alliance
ExSC	Executive Standards Council
FDIS	Final Draft International Standard
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
ILO	International Labour Office
ISA	International Federation of the National Standardizing Associations
ISO	International Organization for Standardization
MB	Member Body
MSS	Management system standards
NC	National Committee
NFPA	National Fire Prevention Association
NGO	Nongovernmental organization
NIST	National Institute of Standards and Technology
NWIP	New Work Item Proposal
OHSAS	Occupational Health and Safety Assessment Series
OHSMS	Occupational Health and Safety Management System
OSH	Occupational safety and health
OSHA	Occupational Safety and Health Administration
PC	Project Committee
PDF	Portable Data Format
PINS	Project Initiation Notification System
SAE	Society of Automotive Engineers
SC	Subcommittee
SDO	Standards Developing Organization

TAG	Technical Advisory Group
TC	Technical Committee
TMB	Technical Management Board
VPP	Voluntary Protection Programs
WD	Working Draft
WG	Working Group

EXECUTIVE SUMMARY

The U.S. Department of Labor, the Chief Evaluation Office, in collaboration with Occupational Safety and Health Administration (OSHA), contracted with Eastern Research Group, Inc. (ERG) to conduct evidence-based research on the development, application, use and effectiveness of Occupational Health and Safety Management Systems (OHSMS) by industry. The DOL's interest in this project is, in part, to understand whether organizations that have implemented an effective OHSMS have better safety and health performance, which supports DOL's mission of ensuring safe and healthful working conditions in U.S. workplaces.

For many years, OHSMSs have been regarded as effective tools in protecting workers from injuries, illnesses, and fatalities (Alsop & LeCouteur, 1999; Bunn III et al., 2001; Conference Board, 2003; Huang et al., 2009; Lewchuk et al., 1996; Smitha et al., 2001; Torp et al., 2000; Yassi, 1998). Since the early 1980s the OSHA's Voluntary Protection Program has recognized and rewarded organizations that implement and maintain exemplary safety and health programs that embody the key elements of more modern OHSMS. OSHA published its Safety and Health Program Guidelines in 1989, to encourage more widespread use of systematic approaches to preventing workplace injuries, illnesses, and fatalities.

In 1999 the first version of an international standard, OHSAS 18001:1999, was published. This was followed by an OHSMS Guideline prepared by the United Nation's International Labour Office (ILO) in 2001. The first U.S. consensus standard, ANSI/AIHA Z10-2005, was published by the American National Standards Institute (ANSI) & American Industrial Hygiene Association (AIHA) in 2005. The standard was revised in 2012. Following the 2012 revision AIHA discontinued its role as the Secretariate for ANSI Z10 and the American Society of Safety Engineers (ASSE)[1] became the new Secretariat for ANSI Z10.   In 2019, the Z10 standard was significantly revised and designated ANSI/ASSP Z10-2019. The most recent development is the publication by the International Organization for Standardization (ISO) of ISO 45001:2018, an effort that began in 2013 and concluded in 2018.

This report describes the processes governing the development of standards for occupational safety and health management systems. ERG's study encompasses a number of research questions and this report addresses the question "Who develops OHSMS consensus standards, and what procedures guide their development?". The evidence-based research for this report included:

- Extensive review of relevant literature,

- In-depth interviews with organizations and individuals involved in standards development, both in the US and internationally, and

- Interviews with professional organizations, and organizations involved with auditing and certifying organizations who have implemented one or more OHSMS consensus standards.

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[1] In June, 2018 the American Society of Safety Engineers changed it name to the American Society of Safety Professionals (ASSP).

Finding 1: OHSMS Consensus standards are based on common core concepts

The individual documents, ANSI/AIHA Z10-2005, ANSI/AIHA Z10-2012, ISO 45001:2018 and ANSI/ASSP Z10-2018, are organized differently and use different language. However. they have core concepts in common. The common components include:

- Emphasis on management leadership
- Robust worker involvement and participation
- Risk assessment and identification
- Hazard and risk control
- The need for competence at all levels of the organization
- Evaluation of the system to identify its achievements and deficiencies
- Continual improvement

The standards are consistent in their overall purpose of improving organizations' occupational health and safety performance. The standards differ significantly, however, in the level of detail in which these core concepts are implemented. Other differences exist also, for example, ISO 45001:2018 and ANSI/ASSP Z10-2019 emphasize integrating OHSMS with other organizational processes such as quality management, environmental management, and energy management.

Finding 2: OHSMS standards development represents a consensus process based on the experience, expertise, and perspective of a large group of well qualified professionals.

The ISO 45001:2018 and ANSI/ASSP Z10-2019 standards represent the consensus of large groups of well-qualified and experienced professionals that come together voluntarily to develop a standard. The resulting standards are based on the collective experience and expertise of the members of the committee. While the standards are often informed by available evidence and scientific data the final decisions on the content are made during a negotiation among the committee members. For instance, the members of ISO Technical Committee 283 (TC 283) that is responsible for ISO 45001 represents more than 90 members from across the globe including 78 member nations who vote on approving or disapproving the standard at its various stages of development. The ANSI/Z10 Committee includes 55 organizations representing industry, labor, academia, government. and professional organizations.

Finding 3: The development process for OHSMS consensus standards is highly structured.

Both ANSI and ISO have elaborate protocols and procedures that govern standards development and ensure consensus. These procedures are designed to ensure that standards represent the consensus of parties that are materially affected by them. The procedures ensure that a balance of interests is maintained, and that no interest group dominates decision-making. Both the ISO 45001:2018 and ANSI/ASSP Z10-2019 standards were developed using a rigorous review process in which each member of the committee provides general, technical, and editorial comments for consideration by the whole committee. Each comment must be addressed and dispositioned such that the committee addresses each comment and revises the document accordingly.

Finding 4: Continual improvement in occupational health and safety is a fundamental value.

The OHSMS standards are founded on the concept of continual improvement. Similarly, the standards development process is designed for continual improvement of the standards themselves. Over time, the standards are updated to reflect current evidence of their effectiveness and to integrate and recognize new concepts and techniques in occupational safety and health. In each update the revised standard is evaluated by a large number of health and safety professionals with a variety of experiences and perspectives. The evolution of the standards will reflect the increased understanding within the professional community of how organizations' performance on worker safety and health can be improved.

1. INTRODUCTION

In 2018, Eastern Research Group, Inc. (ERG), based in Lexington, MA was awarded Order Number 1605DC-18-F-00343 by the U.S. Department of Labor (DOL), the Chief Evaluation Office following a competitive procurement. Under this Order, ERG is tasked with conducting evidence-based research to assess how OHSMS consensus standards were developed, how those standards were adopted by companies, and how various outcomes were associated with the standards. The evidence-based research for this report included:

- Extensive review of relevant literature,

- In-depth interviews with organizations and individuals involved in standards development, both in the US and internationally, and

- Interviews with professional organizations, and organizations involved with auditing and certifying organizations who have implemented one or more OHSMS consensus standards.

The DOL's interest in this project is, in part, to understand whether organizations that have implemented an effective OHSMS have better safety and health performance. Through this study DOL is seeking the evidence that will allow it to understand the relationship between the implementation of OHSMS consensus standards and reductions in occupational injuries, illnesses and fatalities. Key questions to be answered through this effort include:

- Who develops OHSMS consensus standards, and what procedures guide their development?

- What kinds of organizations adopt OHSMS consensus standards, and what are their motivations for doing so?

- What are the perceived and actual benefits and costs of implementing OHSMS consensus standards?

- To what extent does certification to these standards ensure OHSMSs are effective at reducing workplace risk, hazards, injuries, illnesses, and fatalities?

- Are there additional, indirect economic effects associated with OHSMS adoption, such as enhanced productivity or quality, increased worker engagement, reduced turnover, or improved reputation?

This report addresses the first of these questions by describing the organizations that participate in developing OHSMS standards and the processes they follow while doing so. Section 3 of the report describes the framework for developing standards in the U.S, while Section 4 provides similar information that applies to international standards. Section 5 describes the development process behind individual OHSMS standards, both U.S. and international. Section 6 summarizes this research and presents some conclusions.

A companion report to this one describes the organizations and processes involved in certifying conformance to these standards (Eastern Research Group, 2021).

Technical standards in industry serve several purposes. Some exist to inform consumers or provide them assurance of what they are purchasing—for example, standards covering battery sizes, nut and bolt thread patterns, and construction lumber dimensions. Others help with the diffusion of technology and ensure interoperability of components. Examples of these include standards covering personal computer architecture or connections to the electrical grid. Still another type of standard helps provide assurance of process management to control risks and take advantage of opportunities to improve performance. This latter category includes standards for product or service quality, effective environmental management, and control of occupational safety and health risks. This report describes the processes governing the development of standards for occupational safety and health management systems, or OHSMSs. It begins with some background on standards and U.S. and international standards-setting institutions. The main part of the report describes how the different standards covering OHSMSs came to be developed.

Standards can come about through different mechanisms. Some are mandatory, established by government to facilitate procurement (e.g., the U.S. Department of Agriculture's beef quality grades) or to protect the public good (e.g., building codes or standards covering automobile safety equipment). Mandatory standards may also be imposed by firms on their suppliers. Sometimes a standard that is established or followed by one organization (e.g., a manufacturer) simply gets adopted by others (National Research Council, 1995). The PDF format for electronic documents was originally an internal standard used by the Adobe Corporation. As the use of the free Adobe Reader software became widespread, PDF became the de facto standard for printable documents (International Organization for Standardization, 2005). This report focuses on standards developed through a voluntary industry consensus process, of which there are many thousands of examples. Voluntary industry consensus standards are established when groups of affected or interested parties convene, through formal processes, in an attempt to document technical specifications that meet customer, industry and public needs (National Research Council, 1995). These processes, along with examples, are discussed in detail below.

Consensus standards exist at both the national and international level. Section 3 provides an overview of the process in the United States for developing standards. Section 4 discusses how the process works internationally.

2. THE U.S. STANDARDS-SETTING FRAMEWORK

Compared to other countries, the United States has a fairly decentralized standards-setting environment. A 1996 National Institute of Standards and Technology (NIST) study reported over 400 active standards-developing organizations (SDOs) in the United States, which together had developed over 40,000 voluntary, consensus-based standards (Toth, 1996). Not all of these organizations are equally prolific in their standards development activities. Some of the more prominent SDOs are ASTM International,[2] SAE International,[3] and the Electronic Industries Alliance (EIA), each of which has developed over 1,000 different standards (Toth, 1996). Despite their proliferation, not all SDOs and standards are equally influential. The American National Standards Institute (ANSI), the accreditation body for any organization developing an American National Standard (ANS), estimates that the 20 largest SDOs in the U.S. produce 90 percent of the standards (American National Standards Institute, 2019b).[4]

SDOs can fall into several classifications. Technical and professional groups such as ASTM, SAE, and the Institute of Electrical and Electronics Engineers [IEEE] represent one type. These consist of technical experts from a particular profession or discipline, such as a branch of engineering. Their members serve as representatives of the organization that employs them or a professional or trade organization in which they are members. Frequently, however, members are individuals who represent their own consultancy or practice. Funding of these organizations comes primarily from the sale of their standards.

Many trade and industry associations also develop standards, such as the Telecommunications Industry Association, the American Petroleum Institute, and the American Forest and Paper Association. Typically, however, standards setting is not their primary activity and trade association revenues come mostly from association membership dues, not selling standards. Usually, trade association membership consists of individual firms, with each member firm represented by a single individual.

A final type of SDO is the membership organization, which exists for the sole purpose of standards-setting and whose members share an interest in standardization. Examples of these include ASTM and the National Fire Protection Association (NFPA). Professional organizations such as the American Society of Safety Professionals can also be SDOs. Membership in these organizations is not limited to an industry or profession. Publishing and selling standards is one source of revenue for such SDOs.

2.1. The Role of ANSI

All of the activities of SDOs in the U.S. are coordinated by ANSI, a private, nonprofit organization. ANSI:

- Establishes procedures and guidelines for SDOs to follow when developing standards.
- Reviews and accredits SDOs to ensure their adherence to these practices.

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[2] "ASTM" most recently stood for "American Society for Testing and Materials," but the organization changed its name to "ASTM International" in 2001.
[3] Formerly the Society of Automotive Engineers.
[4] American National Standards are standards that have been developed by an ANSI-accredited SDO, conform to the ANSI *Essential Requirements,* and have been approved by ANSI. See also Section 2.2 below.

- Approves standards developed by SDOs and designates them as American National Standards.
- Represents the United States in international standards-development issues.

(American National Standards Institute, no date)

ANSI's procedures and guidelines for standards development emphasize several things. First, every standard should be developed through an open, balanced, consensus-based process. Second, the standard should not duplicate or conflict with existing standards (American National Standards Institute, 2018).

Recognition as an American National Standard can facilitate and quicken a standard's adoption in the marketplace (American National Standards Institute, undated). SDOs wishing to have their standards recognized as American National Standards must follow ANSI procedures and must submit their standards for ANSI review and approval.

This section provides an overview of ANSI's requirements for standards, which are primarily described in *ANSI Essential Requirements: Due Process Requirements for American National Standards* (American National Standards Institute, 2018). Table 1 reproduces the essential requirements verbatim, along with any benchmarks or evidence ANSI would review to determine an SDO's conformance. The subsections that follow the table offer more details.

Table 1. ANSI Essential Requirements for American National Standards

Requirement	Benchmarks
Openness. Participation shall be open to all persons who are directly and materially affected by the activity in question. There shall be no undue financial barriers to participation. Voting membership on the consensus body shall not be conditional upon membership in any organization, nor unreasonably restricted on the basis of technical qualifications or other such requirements.	Evidence of timely and adequate notice of any action to create, revise, reaffirm, or withdraw a standard. Availability of each member's name, affiliation, and interest category (upon request).
Lack of dominance. The standards development process shall not be dominated by any single interest category, individual or organization. Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation to the exclusion of fair and equitable consideration of other viewpoints.	None, unless a materially affected party submits a written claim that a single interest category, individual, or organization dominated the standards development process.
Balance. The standards development process should have a balance of interests. Participants from diverse interest categories shall be sought with the objective of achieving balance. If a consensus body lacks balance in accordance with the historical criteria for balance, and no specific alternative formulation of balance was approved by the ANSI Executive Standards Council, outreach to achieve balance shall be undertaken.	Historically, no single interest category constitutes more than one-third of the membership (for safety standards), or a majority of the membership for non-safety standards. SDOs should define interest categories appropriate to the nature of the standard and, especially, seek inputs from the user community.
Coordination and harmonization. Good faith efforts shall be made to resolve potential conflicts between and among existing American National Standards and candidate American National Standards.	Documentation of good faith efforts to identify and resolve potential conflicts.

Notification of standards development. Notification of standards activity shall be announced in suitable media as appropriate to demonstrate an opportunity for participation by all directly and materially affected persons.	Notification in appropriate media with the goal of encouraging participation. Compliance with ANSI Project Initiation Notification System (PINS) process.
Consideration of views and objections. Prompt consideration shall be given to the written views and objections of all participants, including those commenting on the PINS announcement or public comment listing in *Standards Action.*	Written notification to any objector or commenter of the disposition of the objection or comment and the reasoning for the disposition. Reporting of any unresolved objection and resolution attempts to the consensus body, in order to allow members an opportunity to respond, reaffirm, or change their vote.
Consensus vote. Evidence of consensus in accordance with these requirements and the accredited procedures of the standards developer shall be documented.	Documented evidence of consensus vote, based on SDO's criteria for consensus. Recording and consideration of all negative votes, with comments. Records of changes to original votes.
Appeals. Written procedures of an ANSI-Accredited Standards Developer (ASD) shall contain an identifiable, realistic, and readily available appeals mechanism for the impartial handling of procedural appeals regarding any action or inaction. Procedural appeals include whether a technical issue was afforded due process.	Documentation of appeals and their resolution.
Written procedures. Written procedures shall govern the methods used for standards development and shall be available to any interested person.	NA
Compliance with normative American National Standards policies and administrative procedures. All ANSI-Accredited Standards Developers (ASDs) are required to comply with the normative policies and administrative procedures established by the ANSI Executive Standards Council or its designee.	NA

Source: American National Standards Institute (2018).

2.1.1. Openness

The first requirement is that standard development be an open process. SDOs must allow anyone who is "directly and materially" affected to participate in developing the standard, i.e., anyone who is directly and materially affected can be a member of a standards development committee. Further, SDOs may not impose any undue financial barriers that would inhibit participation. In addition, voting membership on standard development bodies (consensus standards committees) is not limited to specific organizations nor is it based on technical credentials of an individual.

2.1.2. Lack of Dominance

The second requirement is for the process to be free of dominance by any one individual, organization, or interest group. SDOs must ensure all parties have an equal opportunity to express their views and opinions. Along similar lines, SDOs must ensure that a balance of interests is represented. This may require SDOs to actively seek representation from interest groups that are not already participating.

In addition, SDOs are required to:

- Make efforts to resolve conflicts between existing standards and those under development.
- Publicize their standards development activity to encourage and solicit participation.
- Give prompt consideration to written comments of all participants.
- Provide an "identifiable, realistic, and readily available" appeals process to address any procedural issues, including whether a technical issue was properly considered.

To be considered for acceptance by ANSI as an American National Standard, each standard must be approved by the SDO through a documented consensus voting process. Each standard must also meet the administrative requirements and procedures established by the ANSI Executive Standards Council (ExSC).

2.1.3. Balance

The SDO is also required to achieve balance among the interest groups participating in the standards development committee. The point of achieving balance is to avoid the possibility of dominance by any group or perspective. Thus, there is inherent tension between the requirement for openness (any directly and materially affected party can participate) and the requirements to avoid dominance and achieve balance. When forming a standards development committee, the SDO defines the universe of interest groups and determines which groups must be included to achieve a balance of perspectives. Often, for the sake of maintaining a committee size that can be effectively managed, SDOs actively recruit members that represent the variety of interests and perspectives to achieve balance. When some groups are over-represented, the SDO may suggest that similar groups combine and choose one representative to reflect their collective perspective.

2.1.4. Records

The ANSI *Essential Requirements* require SDOs to keep records demonstrating compliance with the requirements and with the SDO's accredited procedures, and to make such records available during audits directed by the ANSI ExSC.

2.1.5. Interpretations

An SDO must maintain an interpretations policy that describes its process for issuing interpretations or responding to requests for interpretations of the standard's applicability.

2.1.6. Accreditation

SDOs whose procedures meet the ANSI *Essential Requirements* and that are incorporated legal entities may apply to ANSI for accreditation. An application for accreditation must include copies of the SDO's standards development procedures and other documentation showing compliance with the *Essential Requirements*. ANSI publishes notification of SDO applications for accreditation in its *Standards Action* publication, along with a call for any comments. Accreditation decisions are made by the ANSI ExSC.

To maintain accreditation, ANSI-accredited SDOs must submit to audits at selected intervals. These audits are arranged by the ANSI Audit Director and conducted according to the ANSI *Auditing Policy and Procedures* (American National Standards Institute, 2015). The ANSI Audit Director reports the findings of the audit to the ExSC.

2.1.7. Changes to SDO Procedures

SDOs must notify the ExSC of any changes to their procedures along with detailed descriptions of the changes. If the ExSC determines the changes to be substantive, notice of the changes will be published in *Standards Action* with a request for comment.

2.2. Approval and Designation of an American National Standard

Any standard developed by an ANSI-accredited SDO in accordance with the *Essential Requirements* may be approved as an American National Standard by the ANSI Board of Standards Review (BSR). The BSR verifies the standard was developed in accordance with the SDO's approved procedures, and that any conflicts with existing standards have been resolved.

Each standard approved as an American National Standard carries on its cover a mark or logo indicating it is an "Approved American National Standard." ANSI publishes standards developed by some (generally smaller) SDOs that lack in-house publishing resources, while most larger SDOs (e.g., ASTM, ASME, IEEE, NFPA) publish their own standards.

2.2.1. National Adoption of an International Standard

ANSI-accredited SDOs may also seek to adopt an international standard as an American National Standard. Procedures for doing so are found in the *ANSI Procedures for the National Adoption of ISO or IEC Standards as American National Standards* (American National Standards Institute, 2007).

2.2.2. Government Use of American National Standards

The public sector also plays an important role in developing standards. Governments at all levels develop and use standards. Some government standards "incorporate by reference" all or portions of industry consensus standards, in effect making them mandatory. Since 1982, federal agencies have been encouraged to participate in voluntary consensus-based processes and adopt standards developed through them, as opposed to issuing their own new standards (Office of Management and Budget, 1993).

3. INTERNATIONAL STANDARDS-SETTING

The same factors that create demand for standards at the national level operate internationally. As trade in goods and services has grown, so has the need for standardization. The first organization established to coordinate standards-setting across national boundaries was the International Federation of the National Standardizing Associations (ISA), founded in 1926 (DeVeaux, 2000). The ISA focused on standards around mechanical engineering such as metrics for tooling and machining, but was never truly a global organization (Yates & Murphy, 2007). After World War II, a new organization was created to replace the ISA—the International Organization for Standardization (ISO).[5,6]

3.1. The ISO

The ISO's mission is to "promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity" (International Organization for Standardization, 2020a). Headquartered in Geneva, Switzerland, the ISO published its first standard in 1951 and has since published over 23,400 standards (International Organization for Standardization, 2020a). ISO members include the national standards bodies of the ISO's 165 member countries. "Full" members (or member bodies) participate and vote in ISO technical and policy meetings. "Correspondent" members may observe the development of ISO standards and strategy by attending ISO technical and policy meetings as observers. "Subscriber" members keep up to date on the ISO's work but cannot participate in it. Full members and correspondent members can sell and adopt ISO International Standards nationally; subscriber members may not (International Organization for Standardization, 2020b).

3.1.1. Country Representation at the ISO

ISO member countries are represented by their National Standards Bodies (International Organization for Standardization, 2020a), most of which are government entities. For example, as an ISO member Canada is represented by the Standards Council of Canada, a federal Crown corporation or state-owned enterprise established by a law of Parliament (Standards Council of Canada, 2019). The United States is an exception in that its representative to ISO is ANSI. ANSI is not a government body but a private, non-profit organization. ANSI was a founding member of the ISO and is influential in how it is managed. ANSI is one of five permanent members of the ISO Governing Council, and one of four permanent members of the ISO Technical Management Board, or TMB (DeVeaux, 2000). The ISO Council meets twice a year and is responsible for the development of ISO's multi-year strategic plan and annual budget, its relations with other external organizations, and other decisions along with the general operations of ISO. The ISO Council consists of the principal officers of ISO and eighteen elected member bodies.

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[5] "ISO" is not an abbreviation (which would not translate well into other languages) but is instead derived from the Greek term *isos*, meaning equal.

[6] An organization similar to but separate from the ISO is the International Electrotechnical Commission (IEC). The IEC is responsible for standards related to electrical, electronic, and related technologies—collectively known as "electrotechnology." The IEC and the ISO operate similarly and have published joint documents establishing procedures for how their work is managed.

The ISO Technical Management Board (ISO/TMB) meets three times each year. It reports to and advises the ISO Council on all matters concerning the organization, coordination, strategic planning, and programming of the technical work of ISO. The ISO/TMB consists of the ISO Vice President for Technical Management and twelve elected member bodies, including ANSI for the U.S.

ANSI is one of the few private sector member bodies, and the United States is one of the few major industrialized countries, not represented by a governmental organization (DeVeaux, 2000). ANSI does not receive direct governmental support for its participation, although many government organizations pay dues as members of ANSI and participate in standards development. ANSI's primary source for funding its participation in ISO activities is its sale of standards and donations. Unlike ISO member country representatives elsewhere, ANSI does not pay travel costs and other expenses for its U.S. delegates to attend ISO meetings (DeVeaux, 2000). ANSI selects and credentials its official U.S. delegates to the ISO and provides them with guidance for participating in ISO committee work, including guidance on achieving consensus (American National Standards Institute, 2013).

3.1.2. ISO Technical Committees

Most of the standards development work of the ISO is done through Technical Committees (TCs). TCs are formed around particular technologies or products (e.g., Fans, TC 117), industries (e.g., Mining, TC 82), or subject matter (e.g., Ergonomics, TC 159). Technical Committees are numbered according to the order in which they were created. To date, over 333 ISO TCs have been established, although not all are currently active (International Organization for Standardization, 2019c). The number of standards developed by each TC varies considerably. For example, ISO TC 22 (Road Vehicles) has developed more than 900 standards, while the median number of standards developed by a TC is 30.

ISO TCs have some flexibility to determine their own organizational structure. For example, if a TC determines its scope is overly broad, it may propose to divide the work among several subcommittees (SCs). TCs and SCs may further divide their work by forming Working Groups (WGs) or ad hoc groups (AHGs) for specific projects. There are over 792 ISO technical committees and subcommittees overseeing standards (International Organization for Standardization, 2020b).

An ISO member body can volunteer to serve as the secretariat of a TC or SC. The secretariat of a TC is approved by the ISO TMB. The TMB also makes the decision when more than one member nation volunteers to serve as secretariat. Each secretariat can nominate a Chairman for the TC, who is appointed by the TMB for six years. The Chairman provides overall management of the TC, including scheduling and presiding over its meetings and overseeing the work of all SCs and WGs. Once appointed, the Chairman serves as a representative of the ISO and may no longer represent his or her national body (International Organization for Standardization, 2020e).

Each national body also indicates whether it will participate actively in the work of the TC or simply observe the work. Active participants, designated as P-members, are obligated to vote on all new work item proposals (NWIPs) and draft and final International Standards. Observers, designated as O-members, observe the process as standards that are being developed, offering comments and advice. They have the right to receive documents, submit comments, and attend meetings, but do not carry voting rights. National bodies can also decide not to participate as either P-members or O-members, in

which case they have none of the rights or obligations outlined above (International Organization for Standardization, 2020d).

ISO procedures also allow for non-country member participation of liaisons, organizations, or individuals who represent other ISO TCs or SCs, or other SDOs. Category A liaisons participate in the work of a TC or SC while Category B liaisons are simply granted access to reports on the work of TCs or SCs, in order to stay informed. The influence of the liaison organizations lies in the development of the standard while the final vote for approval remains with the ISO member bodies (countries)(International Organization for Standardization, 2020b).

3.1.3. The ISO Work Process

Procedures governing the work of TCs are outlined in the ISO/IEC document *Directives, Part 1: Procedures for the Technical Work* (International Organization for Standardization, 2020e). Table 2 describes the various stages of the standards development process.

Note that, before beginning the stages shown in Table 2, a new TC prepares a Strategic Business Plan for its area of activity. The business plan should identify areas within its work program that are expanding, have been completed, are nearing completion, or have not progressed and should be cancelled. The business plan should also evaluate any revision needed to existing standards and provide a perspective on emerging issues. At any time, TCs or SCs may introduce preliminary work items into their work programs that are not ready for further action, such as items related to new technological developments. The TC/SC periodically reviews these items to assess their relevance and need for action.

A NWIP—part of the "Proposal" stage described in Table 2—proposes a new standard, new part of an existing standard, or a Technical Specification or Publicly Available Specification (International Organization for Standardization, 2020f).[7] A TC or SC may receive a NWIP from any national member body, its own secretariat, another TC or SC, a Category A liaison, or the ISO Chief Executive Officer. An NWIP is usually accompanied by a working draft of a document for discussion, along with the identification of a proposed project leader. Approval of an NWIP requires a two-thirds vote of the P-members of a TC. As a general rule, no NWIP may move forward unless there are at least four P-members committed to active participation in the project (for TCs with 16 or fewer P-members) or by five P-members for TCs with 17 or more P-members. Active participation includes nominating technical experts and commenting on working drafts.

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[7] These are essentially draft or preliminary versions of standards that are not ready for approval as ISO standards.

Table 2. Stages of Development of an ISO Standard

Stage	Description
Proposal stage (New Work Item Proposal - NWIP)	The first step in the development of an International Standard is to confirm that one is needed. An NWIP is submitted for a vote by ISO members countries or a relevant TC/SC. The proposal is accepted when a vote of two-thirds is received of the P-members of the TC/SC vote and at least five P-members declare their commitment to participate actively in the project (or four members in the case of a committee with fewer than 16 P-members). A project leader responsible for the work item is normally appointed.
Preparatory stage (Working Draft - WD)	The TC/SC sets up a working group of experts and a convener and working group secretary (if needed) are approved by the TC. The working group prepares the first working draft of the standard. The working group may consider successive working drafts until it is satisfied, and a vote taken to move to a committee draft for the parent committee's review.
Committee stage (Committee Draft - CD)	As soon as a first committee draft is available, it is registered by the ISO Central Secretariat. It is distributed for comments by P-member countries and Successive committee drafts may be considered until consensus is reached on the technical content. Once consensus has been attained, the text is finalized for submission as a draft International Standard.
Enquiry stage Draft International Standard - DIS)	The draft International Standard is circulated to all ISO member bodies by the ISO Central Secretariat with 12 weeks for voting and submitting comments. It is approved for submission as a final draft International Standard if a two-thirds majority of the P-members of the TC/SC are in favor and not more than one-quarter of all votes cast are negative. If it does not meet these approval criteria, the text is returned to the originating TC/SC for further study; a revised document will again be circulated for voting and comment as a draft International Standard.
Approval stage (Final Draft International Standard- FDIS)	The final draft International Standard is circulated to all ISO member bodies by the ISO Central Secretariat for a final yes/no vote with an 8 week voting period. Only editorial comments are accepted. If technical comments are received during this period, they are no longer considered at this stage, but registered for consideration during a future revision of the International Standard. The text is approved as an International Standard if a two-thirds majority of the P-members of the TC/SC are in favor and not more than one-quarter of all votes cast are negative. If it does not meet these approval criteria, the standard is referred back to the originating TC/SC for reconsideration in the light of the technical reasons submitted in support of the negative votes.
Publication stage (International Standard-IS)	Once the final draft International Standard has been approved, only minor editorial changes (if necessary) are introduced into the final text. The final text is sent to the ISO Central Secretariat, which publishes the International Standard.
Review of International Standards (confirmation, revision, withdrawal)	All International Standards are reviewed at least once every five years by the responsible TC or SC.

(Source: International Organization for Standardization, 2020e). Revised with additional information provided by Mr. Victor Toy (Chair), and Ms. Kathy Seabrook (Vice Chair) of the U.S. TAG to ISO PC 283 for ISO 45001, 2020.

Next, the standard enters the preparatory and committee stages. Working drafts of documents developed by ISO TCs in the preparatory stage must follow the procedures outlined in *Directives, Part 2:*

Principles and Rules for the Structure and Drafting of ISO and IEC Documents (International Organization for Standardization, 2018). During preparation, the TC secretariat may propose the formation of a working group to help draft the standard, develop technical reports, or complete other technical tasks. Working groups are comprised of experts nominated by their national standards body. Working group members act in their personal capacity as subject matter experts, not as an official representative of the national standard body that nominated them. In an effort to ensure balance, nominated WG experts are required to classify themselves into one of the stakeholder categories shown in Table 3. If the WG convenor determines there is not adequate stakeholder representation, they may issue a subsequent call for experts. The WG composition is listed in the ISO Global Directory, a central database of individuals authorized to participate in the development of ISO standards (International Organization for Standardization, 2020d).

Table 3. ISO Global Directory Stakeholder's Categories

Category	Title	Typically including:
A	**Industry and commerce**	Manufacturers; producers; designers; service industries; distribution, warehousing, and transport undertakings; retailers; insurers; banks and financial institutions; business and trade associations
B	**Government**	International and regional treaty organizations and agencies; national government and local government departments and agencies, and all bodies that have a legally recognized regulatory function
C	**Consumers**	National, regional, and international consumer representation bodies, independent of any organization that would fall into the 'industry and commerce' category, or individual experts engaged from a consumer perspective
D	**Labour**	International, regional, national, and local trades unions and federations of trades unions and similar bodies the main purpose of which is to promote or safeguard the collective interests of employees in respect of their relationship with their employers This does not include professional associations 1).
E	**Academic and research bodies**	Universities and other higher educational bodies or professional educators associated with them; professional associations 1); research institutions
F	**Standards application**	Testing, certification, and accreditation bodies; organizations primarily devoted to promoting or assessing the use of standards 2)
G	**Non-governmental organization (NGO)**	Organizations that usually operate on a charitable, not-for-profit, or non-profit distributing basis and that have a public interest objective related to social or environmental concerns. This category does not include political parties or other bodies whose main purpose is to achieve representation in government or governmental bodies.

Notes:
 1) Professional associations are regarded as:
associations of individuals practicing, or being closely associated with the practice of, specific professional skills or sets of closely related skills; and having a purpose, at least in part, to advance the development of those skills and the understanding of the arts, sciences, and technologies to which they relate.
2) 'Accreditation' refers to the accreditation of testing and certification bodies.

(Source: International Organization for Standardization, 2020c)

Once a draft document has been completed, it is next submitted to the TC or SC as a first committee draft and is registered by the ISO Secretary General. The committee draft, and successive revised drafts, are submitted for comments and voting until a consensus approval is achieved. At that point the

document is considered a draft International Standard. Generally, the Preparatory Stage involves the development of the working draft by a subgroup before moving forward for input and editing by the larger TC committee in the Committee Stage.

The next step (the enquiry stage) is for the TC or SC to offer P-members and O-members of the technical committee (national standards bodies) the opportunity to comment on the Draft International Standard (DIS). The objective of this stage is to achieve consensus on the technical content. The comment period is usually 8, 12, or 16 weeks long (default is 8 weeks) (International Organization for Standardization, 2020d). Within four weeks of the comment period ending, the secretariat must prepare and circulate a compilation of comments, along with its recommendation of whether to (a) discuss the committee draft and comments at the next meeting, (b) circulate a revised committee draft for consideration, or (c) register the committee draft for the next stage (enquiry). If either of the two latter options is elected, the secretariat must indicate the actions taken in response to each comment and make this available to all members. If any two P-members disagree with the decision to either register the draft or circulate a revised draft (actions b and c above), the committee draft will automatically be subject to discussion at a meeting. Successive committee drafts may go through further revision, comment, and discussion at meetings until a consensus is reached. When reaching the Enquiry Stage, the Draft International Standard is released to all ISO member bodies and opened to the public for comment.

The next phase (the approval stage) culminates in the formal approval of the resulting Draft International Standard if a two-thirds majority of the P-members of the TC/SC are in favor and not more than one-quarter of all votes cast are negative. Finally, the agreed-upon text is published as an ISO International Standard (the publication stage).

3.1.4. Consensus

ISO/IEC Guide 2 defines "consensus" as:

> *General agreement, characterized by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take into account the views of all parties concerned and to reconcile any conflicting arguments. NOTE: Consensus need not imply unanimity.*
>
> (International Organization for Standardization, 2016)

ISO procedures acknowledge that different views will be expressed and discussed while a standard is being developed. The criteria for consensus are based on the absence of "sustained opposition": that is, "views expressed at minuted meetings of committee, working group (WG) or other groups (e.g., task forces, advisory groups, etc.) and which are maintained by an important part of the concerned interest and which are incompatible with the committee consensus" (International Organization for Standardization, 2019a). When committee leadership determines there is sustained opposition to the committee consensus, good faith efforts must be made to resolve it. If these efforts are unsuccessful, the opposition must be registered, but resolution is not a prerequisite to moving the decision forward. Those in opposition are to be informed of their right to use the appeals mechanism.

3.1.5. U.S. Technical Advisory Groups

While ANSI is the official U.S. representative to the ISO, ANSI itself does not provide the expertise needed to represent U.S. positions on ISO standards-setting activities. ANSI policy and procedures, therefore, define a process through which U.S. experts participate in formulating the U.S. position. For each ISO committee to which ANSI registers as a P-member representative, ANSI establishes and accredits a U.S. Technical Advisory Group (TAG).[8,9] Ballots on approving each of the drafts, including TAG comments on the text, are transmitted to the ISO through ANSI. Delegates representing the TAG attend ISO meetings to address and disposition TC/SC comments as members of the working groups (American National Standards Institute, 2019a).

Each U.S. TAG is managed by a TAG Administrator, an organization approved by ANSI to develop the U.S. position on the standard and advocate for that position at the ISO. For this role, ANSI generally chooses the organization responsible for development of American National Standards in the standard area. Thus, the U.S. TAG to ISO TC 20 (Unmanned Aircraft Systems) is administered by the American Institute of Aeronautics and Astronautics, the U.S. TAG to ISO TC 106 (Dentistry) is administered by the American Dental Society, etc. (American National Standards Institute, 2019a). The procedures for TAG administration are outlined in the *Criteria for the Development and Coordination of U.S. Positions in the International Standardization Activities of the ISO and IEC* (see American National Standards Institute, 2019a, Annex B). These criteria are modeled on the ANSI criteria for accredited SDOs and emphasize openness and balance. ANSI provides a set of model procedures that U.S. TAGs may either adopt or use to develop their own procedures (see American National Standards Institute, 2019a, pp., Annex A). All U.S. TAGs are designated and referred to as "U.S. TAG to ISO/TC xx," where "xx" indicates the ISO Committee number.

The formation of any new TAG is announced in the ANSI publication *Standards Action* and may also be announced elsewhere. The TAG Administrator is responsible for identifying, contacting, and inviting the participation of U.S. parties who may be reasonably expected to be, or indicate they are, materially and directly affected by the ISO Committee's work, and invite their participation in the TAG. ANSI procedures specify that U.S. TAGs may not impose any undue financial barriers to TAG participation. Each TAG may charge members administrative fees, but must provide a process for members who request a waiver of the fees.[10] Participation shall not be conditional upon membership in any organization, or unreasonably restricted on the basis of technical qualifications or other such requirements. The TAG Administrator considers applications for TAG membership from interested parties, submits the application to the TAG for approval and sends recommendations for the membership to ANSI for approval. When recommending members, the TAG Administrator is required to consider the appropriateness of each prospective member's participation, the potential for dominance by any single interest, the extent of interest expressed by the applicant, and their willingness to participate actively. Applicants may also ask to participate as observers. Observers are advised of TAG activities, may attend meetings, and may

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[8] An organization's registration as a P-member is contingent upon ANSI determining, in part, that it is competent and willing to serve as administrator of a U.S. TAG (American National Standards Institute, 2019a).
[9] ANSI may initially register as an O-member to facilitate outreach and formation of a U.S. TAG (American National Standards Institute, 2019a).
[10] The U.S. TAG to ANSI for ISO TC 283 (ISO 45001) charges a membership fee ranging from $500 for small organizations or individuals to several thousand dollars for larger organizations. The SDO that serves as secretariat for this TAG (ASSP) can waive membership fees in certain cases.

submit comments for consideration, but are ineligible to vote. Before any final approvals, ANSI publishes a notice in *Standards Action* requesting comment on the proposed TAG Administrator and TAG membership. Any subsequent new member requests are approved by letter ballot or an equivalent formal vote of a majority of the U.S. TAG members (American National Standards Institute, 2019a).

Each TAG Administrator is required to establish a written antitrust policy reflecting the TAG's practice to conduct all business and activity in compliance with applicable antitrust laws. The TAG Administrator must complete ANSI training to ensure compliance with ANSI procedures governing TAG administration and representation of U.S. interests at the ISO. The TAG Administrator must also comply with requirements for ANSI oversight and supervision of its activities. Annually, each TAG Administrator must prepare an Annual Compliance Form and an annual report of its activities which is submitted to ANSI. The report may include or reference minutes of TAG meetings. TAG procedures include a process that any party may follow to submit a complaint concerning the operation or administration of the TAG. The TAG is required to submit copies of any such complaints to ANSI immediately upon receipt, and follow up with copies of its response to the complaint. ANSI may, at its discretion, arrange for audits of U.S. TAGs and TAG Administrators to verify conformance with applicable ANSI and ISO procedures (American National Standards Institute, 2019a).

ANSI procedures require that all "directly and materially" affected parties be afforded the opportunity to participate fairly and equitably, without dominance by any single interest. With respect to dominance, ANSI procedures state the following:

> *Dominance means a position or exercise of dominant authority, leadership, or influence by reason of superior leverage, strength, or representation. The requirement implicit in the phrase "without dominance by any single interest" normally will be satisfied if a reasonable balance among interests can be achieved. Unless it is claimed by a directly and materially affected person that a single interest dominated the standards activity, to the exclusion of fair and equitable consideration of other viewpoints, no test for dominance is required.*

> (American National Standards Institute, 2019a; Annex A: Model Operating Procedures for U.S. TAGs to ANSI for ISO Activities)

4. OHSMS STANDARDS DEVELOPMENT HISTORY

OHSMS standards are examples of a specific type of voluntary consensus-based standard, known as the management system standard. Management system standards define sets of policies, procedures, and practices integrated into an organization that produces reliable outcomes and to drive an organization towards its goals and improvements. Thus, a quality management system helps an organization achieve its quality objectives (e.g., minimize defects, satisfy customers), an environmental management system helps in achieving environmental objectives (e.g., a reduced environmental footprint), and an OHSMS helps in achieving safety and health objectives (e.g., prevention of worker injuries and illnesses and provisions for a safe workplace). This section briefly describes the history of OHSMS and OHSMS standards in the U.S. and internationally.

4.1. OSHA's Voluntary Protection Programs

In the United States, the potential for using a management systems approach to improve safety and health was first tested in 1982 under an OSHA initiative known as the Voluntary Protection Programs (VPP) (Occupational Safety and Health Administration, 1982). Under VPP (a set of programs that remain in place today), workplaces with exemplary safety and health management programs can apply for recognition from OSHA.[11] Recognition is awarded following an onsite review of the workplace program by a team of OSHA specialists, often accompanied by representatives of current VPP worksites.[12] The worksite may then represent itself as an OSHA VPP site, use the VPP logo, and display or fly the VPP flag at the worksite. If the site keeps its injury and illness incidence rate below the average for its industry, it is also exempt from "programmed" OSHA inspections (U.S. Department of Labor, 2020).[13]

OSHA monitored and evaluated the experience of VPP participants and found that most sites had lost-workday case rates significantly below industry averages, while also reporting improvements in worker morale and productivity. In 1989, OSHA decided to make guidance available to other firms wishing to adopt safety and health management programs, resulting in the *Safety and Health Program Management Guidelines*, which were published in the *Federal Register* (Occupational Safety and Health Administration, 1989). OSHA has updated these guidelines, publishing them in a more user-friendly format and rebranding them as the *Recommended Practices for Safety and Health Programs* (Occupational Safety and Health Administration, 2016).

4.2. OHSAS 18001

OHSAS 18001 was developed by the OHSAS Project Group in response to stakeholder interest and need for an OHSMS standard that was auditable and could be applied and recognized internationally. The

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[11] The criteria for acceptance into VPP were developed by OSHA. Although OSHA accepted comments from industry on the program structure, for purposes of this study VPP is not considered an industry consensus standard.

[12] These representatives must undergo training and must qualify as Special Government Employees.

[13] Programmed inspections are a subset of OSHA inspections that select workplaces for inspection based on the hazard category assigned to their industry or the likely presence of hazards OSHA is targeting. Worksites will not be exempt from other inspections, such as those conducted in response to an incident or complaint.

initiative to begin development followed unsuccessful attempts to develop an international consensus for an ISO OHSMS standard. OHSAS 18001 was based upon the existing UK national standard, BS 8800:1996 (*Occupational Health and Safety Management Systems*). This led a group of standards-setting organizations, certification bodies, and other interested parties to convene for the purpose of developing a globally recognized standard, naming themselves the OHSAS Project Group. The secretariat for this group was British Standards Institution (BSI) Management Systems, the for-profit consulting and certification arm of the BSI standards development organization (JR Consultants, 2020).

In its acknowledgments section, the 1999 version of OHSAS 18001 lists 13 organizations that participated in its development (see Table 4). The majority of these were national standards organizations and certification bodies.

Table 4. Listed Members of the OHSAS Project Group, 1999

Organization	Note
Asociación Española de Normalización y Certificación	National certification body of Spain
British Standards Institution	Certification body based in the U.K.
Bureau Veritas Quality International	Certification body based in France
Det Norske Veritas	Certification body based in Norway
International Certification Services	Certification body based in the U.K.
International Safety Management Organisation	Irish safety association
Lloyd's Register Quality Assurance	Certification body based in the U.K.
National Quality Assurance	Certification body based in the U.K.
National Standards Authority of Ireland	National standards body of Ireland
SFS Certification	Certification body based in Finland
SGS Yarsley International Certification Services	Certification body based in the U.K.
South African Bureau of Standards	National standards body of South Africa
Standards and Industry Research Institute of Malaysia	National standards body of Malaysia

Source: (OHSAS Project Group, 1999).

The first version of the OHSAS 18001 standard was published in 1999, followed in 2000 by a companion implementation guide, OHSAS 18002 (*Guidelines for the Implementation of OHSAS 18001*) (OHSAS Project Group, 2000). There is very limited, publicly available information on the process used to develop this standard.

OHSAS 18001 was updated and revised in 2007, with input from a broader and larger group of stakeholders.[14] OHSAS 18001:2007 states that it was drafted "in accordance with the rules given in the ISO/IEC Directives, Part 2" which address the structure, organization, and conventions (e.g., units of measure, use of abbreviations) for standards writers to follow. It should be noted, the ISO/IEC directive does not address ensuring standards are developed without undue influence or dominance, or how to achieve consensus.

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[14] The acknowledgments section of OHSAS 18001:2007 lists 43 organizations that participated in its development.

The forward to OHSAS 18001:2007 listed the more notable changes made with this revision. These included the following (OHSAS Project Group, 2007):

- The importance of "health" was given greater emphasis.
- The standard was more closely aligned with ISO 14001:2004.
- The terms "incident" and "accident" were given the same definition and are interchangeable.
- New requirements for investigating incidents were added.
- A new requirement was introduced for consideration of the hierarchy of controls as part of occupational health and safety planning.
- Management of change was more explicitly addressed.
- A new clause on the "evaluation of compliance" was introduced.
- New requirements for participation and consultation were added.

Following the update, OHSAS 18001:2007 was formally adopted as a British National Standard, superseding BS 8800:2004.

Beginning in 2003, the OHSAS Project Group started periodically surveying certification bodies worldwide to ascertain the number of OHSAS 18001 certifications granted. It is important to note the data year to year is not comparable because in some years, certifications to standards the OHSAS 18001 Project Group deemed "equivalent" to OHSAS 18001 were included. However, certifications to "equivalent" standards represent only a small percent of all certifications after 2005. By the time the last survey was conducted in 2011, over 92,000 certifications had been issued. Of these, roughly 600 (0.7 percent of the total) were granted to organizations in the United States (OHSAS Project Group, 2011). It is important to note that this survey did not include organizations who adopted OHSAS 18001 and other OHSMS standards but chose not to pursue certification (see Figure 1).

Figure 1. Growth in OHSMS Certificates worldwide, 2003–2011.
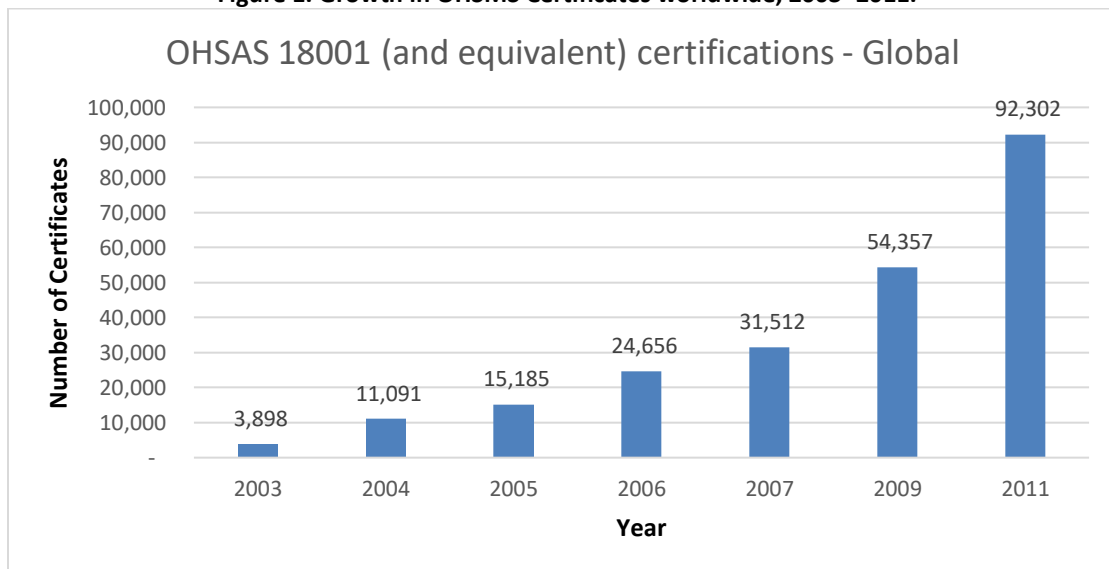
(Source: OHSAS Project Group, 2011).

4.3. ILO OHSMS Guidelines

In 2001, the United Nations' International Labour Office published the *Guidelines on Occupational Safety and Health Management Systems* (International Labour Office, 2001). The document recognizes the potential for reducing workplace risk by encouraging worker consultation and participation, and through labor–management cooperation in designing and implementing an OHSMS. It also advocates integrating occupational safety and health into the organization adopting the guidelines. In accordance with its mission as a tripartite U.N. agency, the ILO developed the guidelines through a workgroup consisting of representatives from government, labor, and employers. Unlike other OHSMS consensus standards, the ILO guidelines are not intended to be supported by an external certification program; conformance is self-declared.

4.4. ANSI/ASSP Z10

The ANSI Z10 Committee was first established in 1999 to begin the process of developing a U.S. standard for OHSMS. At that time the American Industrial Hygiene Association (AIHA) was the secretariat for the ANSI-accredited Standards Committee Z10. Over the next five years, the Z10 committee developed the first American National Standard for OHSMS, designated as ANSI/AIHA Z10-2005. The committee included 42 member organizations representing a variety of interests: labor organizations, industry trade associations, academic institutions, professional organizations, state and federal agencies, and individual employers (American National Standards Institute & American Industrial Hygiene Association, 2005).

ANSI/AIHA updated the Z10 standard in 2012. By then the committee membership had expanded to 53 member organizations, many of which had been on the Z10 standards development committee since its inception in 1999. The wide variety of interest groups involved in developing Z10-2005 were also represented in efforts to revise the standard in 2012. In May 2012, AIHA relinquished the secretariat of the Z10 committee and its copyright to the American Society of Safety Engineers (ASSE). The resulting Z10-2012 standard made relatively few (though important) changes to the Z10-2005 standard. For example, the Z10-2012 contained considerations for life cycle management and process verification which strengthened the implementation and operation of the OHSMS (See sections 5.1.3.1 and 5.1.3.2 of ANSI Z10-2012). With ASSE (now ASSP, the American Society of Safety Professionals) as secretariat, the Z10-2012 was reaffirmed without change in 2017.

ANSI/ASSP published a completely revised version of Z10 in December 2019 (American National Standards Institute & American Society of Safety Professionals, 2019) with two accompanying documents: a guidance and implementation manual (American Society of Safety Professionals, 2019a) and a second guidance manual titled *Keep Your People Safe in Smaller Organizations* (American Society of Safety Professionals, 2019b).

The following description of the development process for ANSI/ASSP-Z10-2019 is based on the published ASSP procedures (American Society of Safety Professionals, 2018).[15] As described earlier, organizations developing or maintaining American National Standards are required to maintain such procedures by the *ANSI Essential Requirements: Due Process Requirements for American National Standards* (American National Standards Institute, 2018). Note that these procedures are designed to produce standards using a consensus process. Where scientific data are available and are known to the standards development committee, they inform the decision making process. Otherwise (in many, if not most cases), the standards are based on the collective professional judgement of the standards development committee members. Standards are developed as committee members identify relevant issues and apply their own experience, knowledge, judgement, and perspective in discussions with other committee members in an effort to achieve a consensus position.

The first step in developing or revising the standard is to establish a pool of entities (organizations, companies, government agencies, standards developers, individuals, trade or labor organizations, or nongovernment organizations, etc.) that are directly and materially affected by the standard and to participate to ensure that standards reflect consensus. ASSP conducts canvasses throughout the process to ensure that those who are materially affected have opportunities to approve, comment, object to, or abstain regarding standards-related activities and products. Section 1 of ASSP's *Operating Procedures for Documenting Consensus to Create American National Standards* contains detailed requirements for conducting standards-related canvasses. The procedures address conducting canvasses, disposition of views and objections, appeals, and requests for interpretations of standards and submitting standards to ANSI for approval.

Section 2 of the ASSP procedures addresses the selection of committee members and the operations of consensus standards committees. The current membership of the Z10 Committee includes 55 organizations, representing a variety of interest categories as shown in Table 5. To achieve balance and avoid dominance, the ASSP procedures specify that no single interest category shall constitute more than one third of the committee members. ASSP reviews the committee balance periodically, and especially when members leave the committee or when new members apply. If it perceives a potential imbalance, it can ask new applicants or current members to join existing organizational members, or ask new applicants to participate as non-voting observers. (Observers may participate in subcommittees, but they do not have voting status on the full committee.)

ASSP, as the Z10 Committee secretariat, has accomplished balance using seven interest categories:[16]

- Professional society (9 percent)
- Industry (34.5 percent)
- Consulting (29 percent)
- Labor organization (11 percent)

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[15] The descriptions of the standards development process for ANSI/ASSP Z10 are also informed by the personal experience and observations of the author of this section, who was present at committee meetings and has first-hand knowledge of the proceedings.

[16] The percentages representing the seven interest categories were derived from the official membership roster for the ANSI/ASSP Z10 Committee as of 2019. A full roster is available from Mr. Tim Fisher, Director, Standards Development and Technical Services, American Society of Safety Professionals

- Technical society (3.6 percent)
- Government (11 percent)
- Insurance (2 percent)

Table 5. Interest Categories Defined in ASSP Standards-Setting Procedures

Interest Category	Definition
Academia (EDU)	A school, college, university, or other higher educational entity or organization with the primary objective of imparting knowledge and education
Consulting (CST)	A professional who is employed externally (either by a firm or some other agency) and provides expert advice in a particular area or specialized field on a temporary basis, usually for a fee.
Consumer (CSM)	Where the standards activity in question deals with a consumer product/services, an appropriate consumer participant's view is considered to be synonymous with that of the individual user—a person using goods and services rather than producing or selling them.
Employee (E/L)	This interest category applies when the standards activity in question addresses subjects of special interest to workers, such as products/services used in the workplace.
Employer (EPR)	An organization with employees that have an interest in the products or services or are purchasers/owners of a product or service.
General interest (GEN)	An organization (association, company, government agency, individual, university) that may/may not have direct use of products/services impacted by an American National Standard, but still has a general interest in this issue due to future implications of a standard, the possibility of citation in other standards, and overall professional interest.
Government (GOV)	A local, state, provincial, or federal government department or agency—including the bodies or associations that represent such entities—that has a legally recognized power to make and/or enforce laws and has regulatory function or responsibility for promulgating, enforcing, or implementing an American National Standard.
Individual expert (EXP)	An individual with a specific interest in the work of the committee. Individual experts shall serve for a renewable term of one year and shall be subject to approval by vote of the consensus body. Individual experts shall be advised of the committee's activities, may attend meetings, and may submit comments for consideration, but shall have no vote.
Industry (IND)	This interest category applies where the standards activity in question addresses/impacts operations of an industrial product operations (e.g., steel production or insulation used in transformers).
Insurance (ISR)	An organization established to identify, assess, and prioritize risks, followed by coordinating and applying resources to minimize, monitor, and control the probability of unfortunate events where an American National Standard addresses/impacts insurance related products and services (e.g., financial services, loss control, risk management, underwriting).
Labor organization (LBO)	An international, regional, national, or local trade union; federation of trade unions; or similar body the main purpose of which is to promote or safeguard the collective interests of employees impacted by an American National Standard in respect of their relationship with their employers.
Manufacturer (MFR)	A manufacturer of products/services affected by the standard, or an entity representing the interests of such manufacturers (e.g., an eyewear manufacturer working on an eye and face protection standard).

Interest Category	Definition
Professional society (PSY)	An organization of professionals in a discipline, representing its membership and/or the practice of the profession.
Technical society (TSY)	An organization representing a specific technical ability, skill, or viewpoint.
Trade association (TAS)	An organization, usually nonprofit, that exists to represent and further the commercial/professional viewpoints and interests of industries producing goods and/or services and protect both the public interest and the interests of professionals.
Training organization (TRO)	An organization specifically addressing the issue of training.
User (USE)	An organization (company, association, government agency) or individual that uses products/services impacted by this American National Standard.
Utility (UTL)	This interest category applies where the standards activity in question addresses/impacts utility-related products and services (e.g., electricity, gas, telephone).

(Source: American Society of Safety Professionals, 2018).

The interest category definitions shown in Table 5 may occasionally overlap, creating a scenario where members with similar purposes and perspectives could be assigned to different interest groups. Such members could in theory represent a voting block that would exceed the one-third criteria and could imbalance and/or dominate a committee. For example, the employee and labor organization interest categories would likely have similar perspectives based on the definition of "labor organization" ("…the main purpose of which is to promote or safeguard the collective interests of employees…"). Similarly, manufacturers, industry, consultants, and trade associations may have similar purposes and interests. In decisions requiring a formal vote where a majority of the committee (more than two-thirds) must agree for approval, the overlap in the interest group definitions could be a cause for concern (American Society of Safety Professionals, 2018).

Despite such potential, this does not appear to have been the case with respect to the ANSI/ASSP Z10 committee. First, the committee is balanced appropriately with respect to the formal interest categories contained in the ASSP *Operating Procedures* (Fisher, 2019). Second, the leadership of the Z10 committee minimizes the impact of coalescing perspectives by consistently applying techniques that account for all viewpoints on the committee. Formal voting is conducted only on the ASSP/Z10 website where new members, committee leadership, and documents are approved. In committee meetings, voting is not allowed. Informal votes in such meetings can only be used to "indicate a sense of the room" on technical issues. If a member voices a significant objection, discussions continue to identify common ground and compromises that allow for general agreement. When discussing an issue where gaining consensus is challenging, the leadership team encourages continued discussions that seek to address concerns of individual members. For example, the robust worker participation provisions in the Z10 standard were the result of many such discussions on the role of worker participation and decision-making in some OHSMS processes.

Once the committee draft standard for Z10 is produced the committee engages in a formal, documented voting process for approval. Members can vote:

- Affirmative without comment
- Affirmative with comment
- Negative with comment
- Abstain (with reasons)

Any comments must reference specific sections and cite the specific text of the standard, state an objection to the standard's content or current form, and suggest revised language. The committee is required to consider and disposition all comments submitted by voting members. Ideally, this disposition process takes place at a committee meeting, though it may also be handled through correspondence.

After approval at the committee level, standards are made available for public comment following public notification in *Standards Action,* the weekly ANSI publication that informs standards developers and the public about current projects and enables effective participation in the standards development process. ASSP also reaches out to its members and uses its social media to solicit public comments. Again, objections and subsequent comments can be submitted by the public and must be dispositioned prior to final publication of the standard. Members of the public that submit a comment(s) are informed in writing of the disposition of their comment(s), the reasons for the disposition, and the right to appeal the disposition.

4.5. ISO 45001

In February 2013, BSI submitted to the ISO Secretary General a NWIP for the development of an International Standard on "Occupational Health and Safety Management Systems—Requirements." This was the fourth attempt to approve a project to develop what eventually became the ISO 45001 standard. The NWIP proposed establishing a new Project Committee (PC) 283, which developed ISO 45001 and later became Technical Committee (TC) 283.[17] with a three-year project timeline. The NWIP recognized the ILO-OSH *Guidelines for Safety and Health Management Systems* as a key document in the field and referred to seven other relevant documents, including the OHSAS 18001 and ANSI Z10 standards, as key documents to consider. Eventually, the development of a final ISO 45001 standard required five years. Table 6 outlines the major steps in the development of the standard and the timeline for the completion of the project.

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[17] The ISO 45001 standard was developed by the project committee (PC 283). Following the publication of ISO 45001, PC 283 transitioned to a technical committee, TC 283 in order to develop a family of standards to support *ISO 45001 Occupational Health and Safety Management Systems – Requirements* standard.

Table 6. ISO 45001 Development Process and Timeline

Stage	Timeline
NWIP	June 2013
Working draft (WD)	Issued January 2014
Committee draft	Issued July 2014 (not approved; received about 2,500 comments)
Second committee draft	Issued March 2015
Draft International Standard	Issued November 2015
Second draft International Standard	Issued May 2017
Final draft International Standard	November 2017
International Standard	March 2018

(Source: PC 283 to ISO 45001, 2015. Revised with information from Mr. Victor Toy, Head of U.S. Delegation, 2020.)

The ISO requires that all management systems standards follow the format and use common standards wording. This is known as 'high level structure.' The required format and wording is contained in the ISO/IEC Directives, *Procedures Specific to ISO,* Annex SL, Section SL9.2 (International Organization for Standardization, 2020d). The stated purpose of Annex SL is:

> *…to enhance the consistency and alignment of MSS by providing a unifying and agreed upon high level structure, identical core text and common terms and core definitions. The aim is that all Type A MSS (and B where appropriate) are aligned and the compatibility of these standards is enhanced. It is envisaged that individual MSS will add additional "discipline-specific" requirements as required.*

(International Organization for Standardization, 2020d)

Annex SL provides common terms and definitions that are required to be used in all ISO management systems standards. The high-level structure format also requires use of 10 major clauses and subclauses with specific wording and required sequence in all ISO management systems standards, as shown in Table 7.

Table 7. Mandatory Sections and Subsections Required by ANNEX SL

Clause	Subclauses
1. Scope	
2. Normative references	
3. Terms and definitions	(This section contains 21 terms and associated definitions that must be used verbatim in ISO management system standards.)
4. Context of the organization	• Understanding the organization and its context • Understanding the needs and expectations of interested parties • Determining the scope of the XXX management system • XXX management system (this subsection contains the requirement for organizations to establish the management system)
5. Leadership[18]	• Leadership and commitment • Policy • Roles, responsibilities, and authorities
6. Planning	• Actions to address risks and opportunities • Objectives and planning to achieve them
7. Support	• Resources • Competence • Awareness • Communication • Documented information
8. Operation	• Operational planning and control
9. Performance evaluation	• Monitoring, measurement, analysis, and evaluation • Internal audit • Management review
10. Improvement	• Nonconformity and corrective action • Continual improvement

(Source: International Organization for Standardization, 2020d).

The advantage of the high-level structure is that it facilitates the integration of various management systems—e.g., quality (ISO 9001), environment (ISO 14001), occupational health and safety (ISO 45001), energy (ISO 50001), and asset management (ISO 55001). Another advantage is that consistency among the ISO management system standards facilitates auditing and certification processes. One possible disadvantage is that the high-level structure assumes that the target audiences for all ISO management system standards are similar and will respond to the language in the same way. This may be the case in technical standards like ISO 9001 and ISO 14001. ISO 45001's substantially greater focus on worker participation, however, may expand the target audience significantly to include workers and their representatives, who may not identify readily with the high-level language mandated by Annex SL.

TC 283 has 78 member bodies (countries) that have agreed to be full voting members of the committee. Another 21 countries participate as observing members, who can attend meetings and may be allowed by the TC 283 convenor to provide technical input but not vote. The TC 283 meetings are well attended.

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[18] ISO 45001 had an additional section under Section 5: 5.4, "Worker Participation." This section was considered essential for OHSMS and its addition was allowed under Annex SL as a discipline-specific requirement.

For example, 97 delegates from 35 participating member countries attended the October, 2019 ISO/TC 283 third meeting in Kigali, Rwanda (International Organization for Standardization, 2019b).

Each member body may establish their own "mirror committee," a group of experts and interested parties in that country that provide input, review, and commentary on TC 283 activities and products through their delegate(s). The mirror committee for each member body designates a delegate(s) to attend the TC 283 meetings and represent their perspectives on any TC 283 votes that are taken. The mirror committees appoint delegates to TC meetings at their sole discretion. They can be from industry, government, labor organizations, or other interested parties. ISO and TC 283 leadership does not have control over choosing country delegates to attend the TC meetings. Each member body's mirror committee represents a range of stakeholder views that formulates their country's position. The delegate(s) chosen to represent their country's position rather than their own personal views (Cottam and Swingewood, 2019).

The U.S. mirror committee, called the U.S. TAG for ISO 45001, has 73 members representing a variety of interest groups. The ASSP is the TAG Administrator supporting the U.S. TAG for TC 283 and applies the approaches to achieving balance and avoiding dominance described in *ANSI Essential Requirements: Due Process Requirements for American National Standards* (American National Standards Institute, 2018) and the *ASSP Operating Procedures* (American Society of Safety Professionals, 2018) described above.

PC 283 developed several drafts of the ISO 45001 standard (see Table 4) and submitted them to member body mirror committees for review and comment. Mirror committees generally have 60 to 90 days to submit comments depending upon the drafting stage the standard is in, i.e., Committee Draft (CD), Draft International Standard (DIS), or Final draft International Standard (FDIS). PC/TC 283 uses a formalized system for member bodies to review and submit comments, including a required form (Figure 2) that identifies (International Organization for Standardization, 2012):

- The commenting member body
- The line number in a draft document for each passage that is commented on
- The clause or subclause number
- The figure or table number
- The type of comment (general, technical, or editorial)
- The commenter's written comment
- The proposed change in language

Figure 2. ISO template for comments and secretarial observations.
(Source: International Organization for Standardization, 2012)

Template for comments and secretariat observations

Date:	Document:	Project:

MB/ NC[1]	Line Number (e.g., 17)	Clause/ Subclause (e.g., 3.1)	Paragraph/ Figure/ Table	Type of comment[2]	Comments	Proposed Change	Observations of the secretariat

1   **MB** = Member body / **NC** = National Committee (enter the ISO 3166 two-letter country code, e.g., CN for China; comments from the ISO/CS editing unit are identified by ******)

2   **Type of comment: ge** = general   **te** = technical   **ed** = editorial

This comment template facilitates the collection of comments in a consistent manner, which allows for efficient and timely distribution to member bodies and subsequent disposition of comments. However, the use of this form for all comments can be somewhat limiting, in that comments must be associated with existing clauses or text identified by line and section numbers. Comments about document organization, omissions, and approach are somewhat more difficult to fit into this comment rubric, though "general" comments are accepted. In addition, this form requires commenters to propose specific language changes to address their concerns. While this facilitates disposition of comments, commenters may be reluctant to make legitimate comments because they do not feel capable of proposing specific language to address their concerns. When specific language is not proposed, comments may be noted, with no action taken, and opportunities to improve the standard can be lost.[19]

Final Draft International Standards must be approved by a two-thirds majority of the participating member bodies with less than 25 percent of member bodies voting to disapprove. Standards are then submitted to the ISO for final approval and publication. ISO 45001: 2018 is an International Standard approved on March 12, 2018. In May 2018, the U.S. TAG to TC 283/ISO 45001 reached consensus to adopt ISO 45001 Occupational Health and Safety Management Systems—Requirements as an American National Standard, in accordance with American National Standards Institute (2007).

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[19] The characterization of the comment template here is based on the observations of one of the authors of this report, a member of the U.S. TAG to ISO PC 283.

5. SUMMARY AND CONCLUSIONS

Consensus standards development is a complex and rigorous process designed to produce standards that represent the common understanding of management system thinking in a country or internationally. It is not fundamentally an evidence-based process. Scientific evidence of the effectiveness of OHSMS consensus standards is sparse. The strength of these standards is provided in the consensus process which is a means to gather together the knowledge and experience of seasoned subject matter experts from specified interest groups (i.e., Table 4), including who have implemented OHSMS and understand the interaction of the essential parts of successful OHSMS.

The standards development processes used by both ANSI in the U.S. and ISO internationally have safeguards to ensure a balance of perspectives. The number of members on the OHSMS consensus standards committees (more than 50 for the ANSI/ASSP Z10 and more than 90 for the ISO TC 283 committees) ensures a variety of perspectives. Delegates for the ISO TC 283 are selected by the member bodies (countries) that best represent the needs, perspectives, and expectations of that country. These are often a government official or a labor representative, but they may also be a representative of a trade group or individual organization. Balance within the U.S. ISO TC 283 TAG and ANSI/ASSP Z10 committee is accomplished through a member approval process that ensures no interest group represents more than one third of the membership. The secretariats of both ISO TC 283 and the ANSI/ASSP Z10 committees are vigilant when it comes to detecting and correcting any dominance by an individual member or group.

Further, the rigorous review process during standards development allows for many opportunities for comment by working group members, committee members, and the public. The diversity of comments submitted through the entire process adds strength to the final consensus standards product. Finally, both the ANSI and ISO processes have mechanisms for formal objections and appeals that are available for any party to have their concerns heard and addressed. Management systems are founded on the principle of continual improvement recognizing even the standard itself may not be perfect for every organization in every case. These standards themselves undergo continual improvement with its period review and updates consistent with its expectations for the organizations adopting these practices for managing health and safety risks and opportunities.

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