OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEMS:

System Certification and Accreditation

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EXECUTIVE SUMMARY

This report is part of an effort by the Department of Labor's Chief Evaluation Office, in collaboration with the Occupational Safety and Health Administration, to understand how and why employers adopt voluntary consensus standards for occupational health and safety (OHS) management. This report focuses on the institutions, organizations, and processes that have emerged to support the certification of occupational health and safety management systems (OHSMS), both in the U.S. and globally. Certification to international standards for the management of occupational safety and health (OSH) can signal to stakeholders that the organization has effective processes in place for identifying, managing, and reducing OHS risks in the workplace. This may help such organizations stand out from competitors, attract and retain a superior workforce, and reduce costs associated with poor OHS performance, such as workers' compensation premiums and injury or illness claims expenses. Regulatory agencies, and stakeholders who may be impacted by regulatory agencies' work, may also be interested in these findings as they consider and evaluate future OSH policies.

The purpose of the report is to provide stakeholders and other interested parties answers to the following questions:

- What does it mean to hold an OHSMS certificate?
- Who issues such certificates and what processes do they follow?
- Who oversees the certification bodies and deems them competent to issue certificates?

A forthcoming report prepared under the same contract as this one provides information on the organizations and institutions that develop these standards, and may be of interest to readers (Eastern Research Group Inc., forthcoming).

Management system standards provide organizations a framework for implementing consensus best practices for managing specific aspects of their business or operations. The international quality management system standard, ISO 9001:1987, was the first such standard to be widely adopted.[1] Besides promoting practices that help users achieve quality goals, adherence to the standard could be verified by external third parties (a certification body, or CB), who would issue the organization a conformance "certificate" following an onsite audit. Acceptance of the ISO 9001 certificate as an indicator of quality has helped reduce the burden of supplier quality verification by customers, both civilian and government, and in turn, promoted trade and growth (Blind et al., 2018).

The success of ISO 9001 in promoting quality management, combined with growing concern over the impact of business on the environment, led to the development of an ISO standard for environmental management systems, ISO 14001:1996 (Jackson, 2012). About the same time, standards began to emerge focusing on the management of occupational health and safety risks. These appeared at both

[1] References to standards within this document include the year of publication (version) unless the reference is to the standard generally. Thus, ISO 9001 refers generally to the quality management system standard while ISO 9001:1987 refers to the initial version of the standard, which was published in 1987.

the national and international level, with the OHSAS 18001 standard becoming the most popular. Most recently, an ISO standard was published, ISO 45001:2018, and its use is likely to increase.[2]

"Accreditation" is the process through which certification bodies become authorized to grant OHSMS certificates. The purpose of accreditation is to ensure consistency in certification practices such that a certified organization can be confident that its certificate will be recognized and accepted anywhere in the world. To facilitate this, accreditation bodies (ABs) participate in a network known as the International Accreditation Forum (IAF). The IAF establishes policies and procedures for accreditation bodies to follow, and operates a Multilateral Recognition Agreement (MLA) designed to promote the mutual recognition of accreditations among MLA signatories.

The accreditation and certification processes provide checks and oversight that ensure a consistent and objective approach is used to assess conformance to OHSMS standards, and to verify that organizations seeking certification have the processes in place to achieve the stated goals of the standard. This in turn ensures that OHSMS certifications issued by an accredited certification body will be recognized and accepted worldwide. When operating properly, the system should be capable of identifying those organizations who are both committed to improving workplace health and safety and equipped with the resources and capabilities to do so, and thus worthy of certification. Further, to maintain certification such organizations must demonstrate not only ongoing conformance to the standard, but continuous improvement in the performance of their system.

Most countries operate a single accreditation body which represents them at the IAF, and most of these are government agencies such as national standards bodies. U.S. members of IAF, however, are nongovernmental organizations. Two U.S. management system accreditation bodies, the American National Standards Institute's (ANSI) National Accreditation Board (ANAB) and the International Accreditation Service (IAS) participate in the IAF as members and MLA signatories. Of these, ANAB is most active in accrediting U.S. certification bodies while IAS accredits mostly non-U.S. certification bodies.[3]

Accreditation is granted to certification bodies within specific "clusters" or groups of industries, requiring the certification body and its auditors to have knowledge of those industries and their hazards. Accreditation of a certification body involves initial and ongoing reviews by the accreditation body, using both office assessments and "witnessed" audits. During office assessments, the accreditation body interviews management and audit team members, reviews records, and verifies the certification bodies is following all administrative procedures. This includes the certification bodies' processes for:

- Recruiting, training, and evaluating auditors
- Determining the number of auditor-days required for each audit
- Reviewing and approving audit reports
- Issuing, suspending, and withdrawing certifications
- Responding to appeals and complaints

[2] Most existing OHSAS 18001 certifications are migrating to ISO 45001:2018.

[3] As of 2020, ANAB had accredited 26 CBs for ISO 45001:2018, of which 16 are in the U.S. (see https://anabdirectory.remoteauditor.com). IAS had accredited 48 certification bodies for ISO 45001:2018, of which six are in the U.S. (see https://www.iasonline.org/search-accredited-organizations-2)

During witnessed audits, accreditation body staff participate as observers during certification audits of the certification body's clients.

The role of the certification body is to verify that the organization seeking certification has implemented all elements of the OHSMS standard and is on the path to achieving its intended outcomes, i.e., improved management of occupational health and safety risks. Initial certification audits include a review of the client's management system documentation, review of the client's understanding of the standard being audited, gathering of information on the scope of the client's management system (e.g., information about the site, processes and equipment, or applicable regulatory requirements), and an evaluation of whether the client organization conducts its own audits and management reviews. The second stage is an onsite audit evaluating the client's implementation of the management system, in which the certification body gathers information on how the management system conforms with the applicable standards and regulatory requirements. Each audit concludes with a closing meeting and an audit report, which contains descriptions of any nonconformities found and the evidence supporting such findings. Upon successful closure of any findings, the certification body may issue the certificate. ISO 45001:2018 certifications are valid for a period of three years. Annually, however, each customer is subject to a surveillance or verification audit. A full recertification audit is required after three years.

While the certified organization is free to publicize its certification and use its certificate for marketing and other purposes, subject to certain guidelines, it is important to note that the certificate belongs to the certification body. It can be suspended or withdrawn at any time if the organization fails to maintain all requirements for certification. Likewise, the certificates issued by the certification body remain accredited only as long as the certification body maintains its accreditation.

1. INTRODUCTION

The adoption and use of voluntary consensus standards in industry is growing. While consensus standards serve many purposes, a primary one is to signal to stakeholders that the adopting organization conforms to a set of recognized best practices. Management system standards are a distinct category of consensus standards. Unlike standards for products or people, management system standards describe how an organization manages a particular aspect of its operations, in order to achieve its objectives.

The first management system standard, BS 5750:1979, was published in 1979 by the British Standards Institute (BSI) to help alleviate onerous quality inspections and oversight of suppliers to the UK Ministry of Defense. It defined a set of policies, procedures and practices that organizations could apply to identify and solve quality problems and achieve quality objectives. Adoption of the standard soon spread to other industries, and in 1987 an international quality management system (QMS) standard, ISO 9001:1987, was published by the International Organization for Standardization (ISO).[4,5]

The success of ISO 9001, combined with growing awareness of the impact of business on the global environment, led to the development of a standard for environmental management systems (EMS), ISO 14001:1996, in 1996 (Jackson, 2012).[6] Then in 1999, BSI published OHSAS 18001:1999, the first standard covering occupational safety and health management systems (OHSMS). Adoption of the standard grew beyond the UK and soon became the de facto international OHSMS standard.[7] In 2005, the American National Standards Institute (ANSI), supported by the American Industrial Hygiene Association (AIHA), published a U.S. national standard for OHSMS, ANSI/AIHA Z10-2005. Most recently, in 2018, the ISO published ISO 45001:2018. This led BSI to agree to withdraw OHSAS 18001 by March 2021; any organizations certified to OHSAS 18001 wishing to retain an OHSMS certification will have to transition to ISO 45001:2018 by that date.

An important aspect of all management system standards is the existence of a process for assessing conformance to the standard through a third-party assessment, or audit. These assessments are conducted by certification bodies (CBs). Organizations seek such assessments to satisfy both internal and external stakeholders. Internally, the assessment provides an outside perspective on how the system has been implemented and is performing, and often identifies opportunities for improvement. Externally, the assessment can be used to demonstrate to stakeholders – such as customers, business partners, communities, or government entities – that the organization meets certain standards, eliminating the need for them to verify performance on their own.

[4] "ISO" is not an abbreviation (which would not translate well into other languages) but is instead derived from the Greek term *isos*, meaning equal.
[5] According to ISO, in 2019 over 883,000 organizations representing 1.2 million sites had been certified in conformance with ISO 9001 (International Organization for Standardization, 2020).
[6] The 2019 ISO survey found over 312,000 organizations representing 489,000 sites had been certified in conformance with ISO 14001 (International Organization for Standardization, 2020).
[7] The OHSAS Project Group estimates that in 2011 (the last year such a survey was conducted) over 93,000 organizations worldwide had adopted OHSAS 18001 or "similar" standards (OHSAS Project Group, 2011).

This report describes the process through which certification bodies become accredited to assess and certify an organization's conformance to OHSMS standards such as OHSAS 18001:2007 or ISO 45001:2018. Figure 1 depicts, from bottom to top, the relationship between the organization seeking certification, the certification body, the accreditation body (in the United States, the ANSI National Accreditation Board [ANAB] or International Accreditation Service [IAS]), and the organization that ensures global recognition of the accreditation process, the International Accreditation Forum (IAF). Figure 1 also shows, on the right, the standards developing organizations (SDOs), which may be national or international bodies. A companion research report contains more detail on these SDOs and the processes they follow to develop OHSMS standards (Eastern Research Group Inc., 2020).

> ***Accreditation*** is the process through which a certification body demonstrates it has the competence and capacity to undertake assessments and determine conformance to a particular standard.
>
> ***Certification*** of an organization's management system is granted following an assessment by a certification body and their determination that the system conforms to the standard against which it is being assessed.

In brief, an organization seeking certification of its OHSMS (e.g., to ISO 45001:2018) contracts with a certification body (CB), also known as a conformity assessment body (CAB) or a registrar.[8] The CBs are accredited by an accreditation body (AB), which verifies their adherence to various auditing standards, procedures, and rules. CBs are usually accredited in the country where they are domiciled, but they may choose to become accredited elsewhere (e.g., a non-U.S. CB may choose to be accredited by a U.S. AB), by multiple ABs, or not at all. CBs without accreditation, however, may find their market more limited. Most countries that operate CB accreditation processes do so through a single, national AB . Most of these, in turn, are members of the International Accreditation Forum (IAF), an organization that establishes rules and procedures for the operation of ABs around the world. In the U.S., the ANSI National Accreditation Board (ANAB) is the dominant AB but a second organization, the International Accreditation Service (IAS) has been providing accreditation services since 2013 (Section 2.4 provides more details about these organizations).

The ISO/IEC 17021 standard[9] establishes the basic requirements for organizations operating management system certification programs and is the primary standard that ABs use to assess and verify how each CB operates and manages its auditing practice. ISO/IEC 17011, in turn, contains similar requirements for ABs and is used by the IAF to determine whether an AB is eligible for IAF membership.

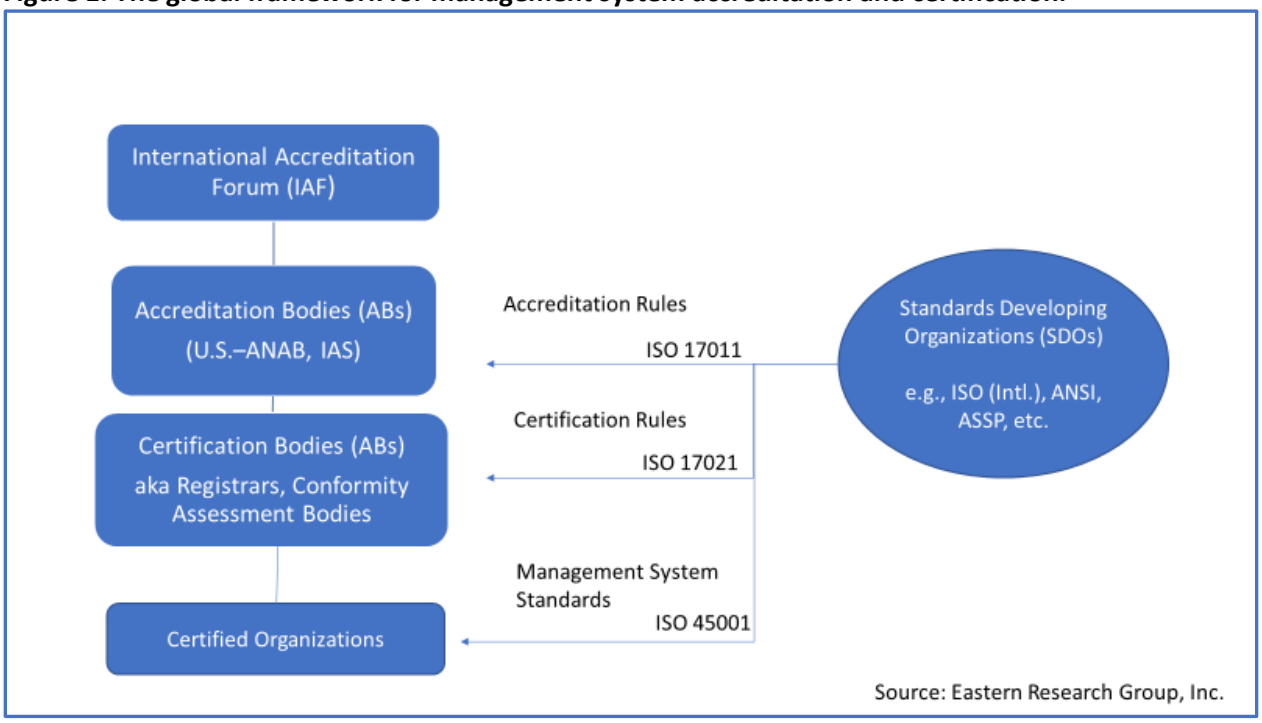
The overall goal of this certification and accreditation "ecosystem" is to facilitate trade through global recognition and harmonization of an organization's management system. Each organization certified by an accredited CB is assured that its management system will be recognized and accepted worldwide. Thus, IAF's motto: "certified once, accepted everywhere."

[8] This document uses the terms "certification body," "conformity assessment body," and "registrar" interchangeably. "Certification body" is more commonly used in the United States, while "conformity assessment body" is found in most standards documents.

[9] The International Electrotechnical Commission, or IEC, is a sister organization to the ISO that supports development of technical standards covering the manufacturing and testing of electrical, electronic, and related products. The organizations have jointly developed and follow numerous standards, including both ISO/IEC 17021 and ISO/IEC 17011.

The sections below describe each component of the accreditation/certification framework in more detail, with a focus on the organizations involved and the procedures and rules that govern their operations. Section 2 introduces the International Accreditation Forum (IAF), an organization that assures global recognition of certifications accredited by IAF members. Section 3 provides an overview of ISO/IEC 17001, the standard that establishes requirements for ABs. Section 4 describes ANAB and the policies and procedures it follows in granting accreditations. Section 5 discusses ISO/IEC 17021, the standard that establishes requirements for CBs. Section 6 presents a summary and conclusions.

Figure 1. The global framework for management system accreditation and certification.



2. THE INTERNATIONAL ACCREDITATION FORUM

The IAF is a global association of ABs, based in the Netherlands. The organization was founded in 1993 at a meeting of six organizations: ANSI and RAB (now ANAB) from the U.S., RvA (Netherlands), UKAS (UK), JAS-ANZ (Australia-New Zealand), SCC (Canada), and JAB (Japan) (Dougherty, 2013).[10] IAF performs three primary functions:

1. Serve as a forum for developing best practices for conformity assessment.

[10] ANSI = American National Standards Institute; RAB = Registration Accreditation Board; RvA = Raad van Accreditatie (Dutch Accreditation Council); UKAS = United Kingdom Accreditation Service; JAS-ANZ = Joint Accreditation System of Australia and New Zealand; SCC = Standards Council of Canada; JAB = Japan Accreditation Board.

2. "Accredit the accreditors," to ensure that ABs—its members—only accredit CBs that are competent and free of conflicts of interest.

3. Operate a Multilateral Recognition Arrangement (MLA), through which ABs agree to mutually recognize accreditations granted by other IAF member bodies (International Accreditation Forum, 2016b). This is one of the most important functions of the IAF.

IAF also operates a Development Support Program, offering technical support to ABs from developing countries. An important, recent IAF initiative is the development of a global database of CBs and management system certifications for each CB. The database is known as IAF CertSearch (https://www.iaf.nu/articles/Update_on_the_IAF_Database_of_Accredited_Certifications/618).

2.1. The IAF Multilateral Recognition Arrangement

ABs apply for IAF accreditation within specific areas of standard-setting (referred to as scopes), and for specific standards within those scopes. Thus, an organization could be accredited for food safety standards, which fall in the product certification scope. Another organization may be accredited under the management system scope, and within that scope for quality and environmental standards. Multiple accreditations are also possible and common.

As seen in Table 1, the IAF MLA is structured around five levels. At Level 1, ISO/IEC 17011 is applied to all ABs. Levels 2 and 3 define the area of accreditation activity, along with the corresponding normative documents. Thus, bodies seeking management systems accreditation are required to comply with both ISO/IEC 17011 and ISO/IEC 17021. Levels 4 and 5 define further sub-areas of activity (e.g., EMS, QMS) and the corresponding normative documents (ISO 9001, ISO 14001). (Presumably, this IAF document showing the structure of the MLA will be updated in the near future to reflect adoption of ISO 45001:2018.)

Table 1. Structure of the IAF MLA

Level 1	ISO/IEC 17011							
Level 2	Product certification	Management systems					Certification of persons	Validation and verification
Level 3	ISO/IEC 17065	ISO/IEC 17021					ISO/IEC 17024	ISO 14065
Level 4	Global G.A.P. IFA general regulations	ISO/TS 22003 (FSMS)	ISO/IEC TS-17021-3 (QMS)	ISO/IEC TS-17021-2 (EMS)	ISO/IEC 27006 (ISMS)		Future endorsed normative documents	
Level 5	Global G.A.P. IFA CPCCs	ISO 22000	ISO 9001	ISO 14001	ISO/IEC 27001	ISO 13485		

Level 1 is the endorsed normative document for ABs.
Levels 2 and 3 are the main scopes and endorsed normative documents.
Levels 4 and 5 are the sub-scopes and endorsed normative documents.
(Source: International Accreditation Forum, 2015b)

2.2. The IAF Membership Process

ABs achieve IAF MLA signatory status following an in-depth review of their operations by a peer evaluation team. However, IAF delegates most of these reviews to IAF-recognized Regional Accreditation Groups such as the European Co-operation for Accreditation, the Asia Pacific Accreditation Cooperation Incorporated, and the InterAmerican Accreditation Cooperation, or IAAC (International Accreditation Forum, n.d.). Section 2.5 discusses the IAAC and presents more details on the peer review process.

2.3. IAF Documents

2.3.1. Policies, Procedures, and Informative Documents

IAF has issued a series of **policies** that reflect governance requirements it expects members to adhere to, specify IAF internal operational procedures, or represent IAF viewpoints on particular issues. Table 2 lists these policy documents. For this study, IAF PL 1 *(Code of Conduct)* and PL 6 *(Memorandum of Understanding)* are the most relevant and are highlighted in the table. The *Code of Conduct* emphasizes adherence to all applicable laws and regulations, impartiality, treatment of confidential business information, and the obligation to report actual or potential conflicts of interest that may arise as a result of any member's fulfillment of IAF membership duties (International Accreditation Forum, 2009).

The *Memorandum of Understanding* serves as the IAF membership agreement and communicates the objectives of the IAF, the rights of IAF members, and the obligations of the IAF members. Principal among these obligations are to support the acceptance of "the equivalence of the accreditations granted by signatories to the IAF MLA that are covered by the scope of the MLA" and "accredited conformity assessment results granted by bodies accredited by Accreditation Body Members that are signatories to the IAF MLA, and covered by the scope of the MLA" (International Accreditation Forum, 2016c).

Table 2. List of IAF Policy Documents

Document Number and Title	Description
IAF PL 1:2009, Code of Conduct for Members of the IAF	Outlines the broad principles of legal and ethical business conduct embraced by IAF. This Code signifies voluntary assumption by IAF members of a standard of conduct that may often be above and beyond the requirements of the law. Acceptance of this Code of Conduct is mandatory for IAF members as a condition of membership of IAF.
IAF PL 2:2015, Bylaws of the International Accreditation Forum Inc.	Bylaws of the International Accreditation Forum Inc.
IAF PL 3:2016, Policies and Procedures for the Expansion of the Scope of the IAF MLA	Provides policies and procedures for the expansion of the scope of the IAF MLA based on publicly owned (including Regulatory) Normative Documents and privately owned Sector Schemes.
IAF PL 4:2018, Rules for IAF Membership Fees	This document sets out the rules for calculating and collecting membership fees for IAF members.
IAF PL 5:2016, Structure of the International Accreditation Forum Inc.	Sets out the structure of the IAF, the responsibilities and duties of the IAF Board, Executive and Officers, as well as the Terms of Reference of the IAF Committees and Subcommittees.
IAF PL 6:2016, IAF Memorandum of Understanding	The IAF Memorandum of Understanding (MoU) is the basic membership document of IAF. All members of IAF are required to sign the MoU and to abide by the commitments they make in it.
IAF PL 7:2015, IAF Quality Manual	Describes the management system established to ensure the effective implementation of the Mission, policies and objectives of the International Accreditation Forum.
IAF PL 8:2016, Rules for the Use of the IAF Logo	Sets out the rules for the use of the IAF Logo.
IAF PL 9:2019, General Principles for the Use of the IAF CERTSEARCH Mark	This document describes principles on the use of the IAF CERTSEARCH Mark by IAF MLA Signatory Accreditation Bodies under main scope ISO/IEC 17021-1, CBs accredited by IAF MLA Signatory ABs, and entities certified by CBs accredited by IAF MLA Signatory ABs.

Note: Document descriptions are taken verbatim from the IAF website https://www.iaf.nu/articles/Policy_Documents/40.

IAF also issues **procedures** (Table 3), which are to be followed in implementing the IAF program. Few of these apply directly to IAF member AB operations and instead apply mainly to the IAF itself.

Table 3. List of IAF Procedures

Document Number and Title	Description
IAF PR 1: 2015, Procedure for the Investigation and Resolution of Complaints	IAF has adopted the procedure set out in this document for the investigation and resolution of complaints made to IAF. Complaints received may concern decisions and activities of IAF or IAF members, or conformity assessment bodies (CABs) accredited by IAF Accreditation Body Members.
IAF PR 2:2018, General Procedures for the Development of IAF Documents	This procedure sets out the rules for the development and approval of IAF documents.
IAF PR 3:2005, Procedures for IAF General Assembly Meetings	This procedure sets out the formal rules for the management of the IAF General Assembly Meetings.
IAF PR 4:2015, Structure of the IAF MLA and List of IAF Endorsed Normative Documents	Describes the structure of the IAF MLA and publishes the list of IAF endorsed normative documents, including international standards, as required by IAF PR2
IAF PR 5:2018, Procedure for Handling Applications for MoU Membership in IAF	This document describes procedures to be followed in the processing of applications from Accreditation Bodies, Industry and Certification Body Associations, and Regional Accreditation Groups for Memorandum of Understanding (MoU) Membership status in IAF.
IAF PR 6:2011, Assignment of IAF Liaisons	Procedure for the appointment of individuals to represent IAF or act as contact persons between organisations where IAF and its members have special interests

Note: Document descriptions are taken verbatim from the IAF website https://www.iaf.nu/articles/Procedures_Documents/42.

Periodically, IAF develops **informative documents** that represent consensus best practices of IAF members. These are provided to members with the recommendation they be used, but members are not under any obligation to do so. The current list of IAF informative documents is shown in Table 4. The highlighted ones are described below.

Table 4. List of IAF Informative Documents

Document Number and Title	Description
IAF ID1:2014, IAF Informative Document for QMS and EMS Scopes of Accreditation	This informative document is applicable for QMS and EMS management systems scopes of certification and is meant to facilitate the consistent application of Clause 7.1.1 of ISO/IEC 17021: 2011 and Clause 7.21. of ISO/IEC 17011 requirements by Accreditation Bodies.
IAF ID 3:2011, Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations	Informative document intended to provide guidance to ABs and CABs on the appropriate course of action for the proper maintenance of accreditation and certification when extraordinary events or circumstances beyond the control of the organization happen.
IAF ID 4:2012, Market Surveillance Visits to Certified Organizations	Informative document intended to provide suggestions about how short market surveillance visits might be used by accreditation bodies or others in order to complement traditional oversight techniques.
IAF ID8:2014, IAF Informative Document for the Transition of Food Safety Management System Accreditation to ISO/TS 22003:2013 from ISO/TS 22003:2007	Informative document to facilitate transition of ISO/TS 22003:2007 to ISO/TS 22003:2013.
IAF ID 12:2015, Principles on Remote Assessment	This document provides suggestions about how to plan, manage, and facilitate remote assessments used by Accreditation Bodies in order to complement traditional oversight techniques
IAF ID 13:2017, IAF Medical Device Nomenclature (IAF MDN) Including Medical Device Risk Classifications	This document, developed to support of IAF MD8 and MD9, provides long established medical device names and classifications, where risk classifications do not exist in the Global Medical Device Nomenclature (GMDN).

Note: Document descriptions are taken verbatim from the IAF website https://www.iaf.nu/articles/Informative_Documents_/32.

While none of these informative documents have specific applicability to OHSMS auditing, several have taken on more importance under the COVID-19 pandemic. For example, IAF ID 3 *(Extraordinary Events and Circumstances)* outlines how ABs and CBs shall plan for and respond to extraordinary events or circumstances that may prevent the CB from carrying out planned audits (International Accreditation Forum, 2011). The document specifically includes pandemics as an example of such events or circumstances. Another informative document, IAF ID 12 *(Remote Assessments),* provides guidance for conducting audits (or portions of audits) using remote technology (International Accreditation Forum, 2015a). IAF ID 12 acknowledges the potential for technology to facilitate efficient and effective review of some aspects of the management system. Remote auditing has taken on increased importance during the pandemic. Section 4.1.2 below includes details on ANAB guidance for conducting remote assessments during the pandemic.

2.3.2. Mandatory Documents

IAF most directly affects ABs themselves through the **mandatory documents** (MDs) it has issued (listed in Table 5). A number of these, in fact, directly address auditing of OHSMS. ABs that are members of IAF are *required* to use these documents when examining and accrediting the audit program of CBs. The MDs highlighted in the table are discussed in more detail below.

Table 5. IAF Mandatory Documents

Document Number and Title	Description
IAF MD 1:2018, IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization	This document is for the audit and, if appropriate, the certification of management systems of organizations with a number of sites with a single management system.
IAF MD 2:2017, IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems	This document provides normative criteria on the transfer of accredited management system certification between certification bodies. The criteria may also be applicable in the case of acquisitions of certification bodies accredited by an IAF or Regional MLA signatory.
IAF MD 3:2008, Advanced Surveillance and Recertification Procedures (ASRP)	This document provides normative criteria for advanced surveillance and recertification procedures (ASRP) for consistent application of clause 9.1.1 of ISO/IEC 17021:2006 for determining subsequent adjustments to the audit program. This document addresses only Quality Management Systems (QMS) and Environmental Managements Systems (EMS), in which IAF members have had experience of implementing ASRP or its predecessor methodologies. The use of ASRP is not mandatory, but if an accreditation body wishes to permit their accredited certification body and its client(s) to opt for the use of ASRP, it is a requirement of IAF that the certification body and its client(s) conform to this document and be able to demonstrate conformity to the accreditation body.
IAF MD 4:2018, IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes	The scope of this document is for the auditing/assessment of management systems, persons and product and is applicable to conformity assessment bodies and accreditation bodies. The use of ICT is not mandatory and may be used for other types of conformity assessment activities, but if used as part of the audit/assessment methodology, it is mandatory to conform to this document.
IAF MD 5:2019, Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems	This document is mandatory for the consistent application of the relevant clauses of ISO/IEC 17021-1 for audits of quality, environmental, and occupational health and safety management systems. All clauses of ISO/IEC 17021-1 continue to apply and this document does not supersede any of the requirements in that standard.
IAF MD 6:2014, Application of ISO 14065:2013	ISO 14065:2013 provides to Greenhouse Gas (GHG) programme administrators, regulators and accreditors, a basis for assessing and recognising the competence of validation or verification bodies (V/VBs). This Mandatory Document provides additional application guidance to enable harmonisation by IAF members for the assessment of validation or verification bodies (V/VBs) against ISO 14065 and related standards.
IAF MD 7:,2010 Harmonisation of Sanctions	Mandatory document which clarifies situations where sanctions are to be applied to applicant or accredited Conformity Assessment Bodies.
IAF MD 8:2017, Application of ISO/IEC 17011:2004 in the Field of Medical Device Quality Management Systems (ISO 13485)	This document specifies normative criteria for Accreditation Bodies assessing and accrediting Conformity Assessment Bodies which provide audit and certification to ISO 13485, in addition to the requirements contained with ISO/IEC 17011:2004. It is also appropriate as a requirements document for the peer evaluation process for the IAF Multilateral Recognition Arrangement (MLA) among Accreditation Bodies.
IAF MD 10:2013, IAF Mandatory Document for Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021: 2011	Provides a harmonised approach to how Accreditation Bodies assess a Certification Body's management of competence in accordance with ISO/IEC 17021:2011.
IAF MD 11:2019, IAF Mandatory Document for the Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems	This document provides requirements for the application of ISO/IEC 17021-1 for the planning and delivery of audits of IMS and, if appropriate, the certification of an organization's management system(s) against two or more sets of audit criteria/standards. Version 2 was published 03 July 2019 after agreement by letter ballot to change the application date to 17 January 2021.

Table 5. IAF Mandatory Documents

Document Number and Title	Description
IAF MD 12:2016, Accreditation Assessment of Conformity Assessment Bodies with Activities in Multiple Countries	Provides requirements for the consistent application of Clause 7 of ISO/IEC 17011 regarding an Accreditation Body (AB)'s Assessment of Conformity Assessment Bodies (CAB)'s that provide certification in countries outside the country in which their head office is located.
IAF MD 13:2015, Knowledge Requirements for Accreditation Body Personnel for Information Security Management Systems (ISO/IEC 27001)	Provides specific knowledge requirements for Accreditation Body personnel to harmonize their application of Clause 6.2.1 of ISO/IEC 17011:2004 for the accreditation of bodies providing audit and certification of information security management systems (ISMS) to ISO/IEC 27001.
IAF MD 14:2014, Application of ISO/IEC 17011 in Greenhouse Gas Validation and Verification (ISO 14065:2013)	Provides normative criteria for Accreditation Bodies assessing and accrediting GHG validation and verification bodies to ISO 14065, in addition to the requirements contained within ISO/IEC 17011. It is also appropriate as a requirements document for the peer evaluation process for the IAF Multilateral Recognition Arrangement (MLA) among Accreditation Bodies.
IAF MD 15:2014, IAF Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance	Provides the "indicators" which Accreditation Bodies shall require accredited Management System Certification Bodies to report to them on a periodic basis.
IAF MD16:2015, Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies	This document specifies normative criteria for Accreditation Bodies assessing and accrediting CABs which provide audit and certification of FSMS, in addition to the requirements contained with ISO/IEC 17011. It is also appropriate as a requirements document for the peer evaluation process for the IAF Multilateral Recognition Arrangement (MLA) among Accreditation Bodies.
IAF MD 17:2019, Witnessing Activities for the Accreditation of Management Systems Certification Bodies	This document is mandatory for the consistent application of the relevant clauses of ISO/IEC 17011:2017 Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies.
IAF MD 20:2016, Generic Competence for AB Assessors: Application to ISO/IEC 17011	This document ensures the consistent and harmonized application of ISO/IEC 17011 for defining the generic competence for assessors.
IAF MD 21:2018, Requirements for the Migration to ISO 45001:2018 from OHSAS 18001:2007	This document provides requirements for the migration from OHSAS 18001:2007 to ISO 45001:2018.
IAF MD 22:2019, Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)	This document is mandatory for the consistent application of ISO/IEC 17021-1:2015 for the accreditation of Certification Bodies providing certification of Occupational Health and Safety Management Systems (OH&SMS).
IAF MD 23:2018, Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies	This document relates to entities, performing and/or managing management system certification activities, on behalf of Certification Bodies (CBs) holding accreditation, which are not wholly or partly owned or employed by the CB.

Note: Document descriptions are taken verbatim from the IAF website https://www.iaf.nu/articles/Mandatory_Documents_/38.

IAF MD 5:2019, Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems. This document establishes a requirement for CBs to determine the audit duration (number of auditor-days) for QMS, EMS and OHSMS audits, and to do so as part of initial client review. The intent is to ensure consistency in audit duration across the industry, such that clients would not expect to receive widely varying quotes based on differences in audit length. The document

includes requirements for estimating the time required for Stage 1 and Stage 2 of an initial audit and of surveillance audits and recertification audits.[11]

Annex C to IAF MD5 provides a table to assist in determining the number of audit days based on two factors: the effective number of personnel at the site and the "complexity" category of the facility being audited. These are defined as follows:

1. "High" complexity operations: activities by many natural resource extraction and processing industries (offshore fishing, mining and quarrying, oil and gas exploration, chemical manufacturing, automotive manufacturing, other heavy manufacturing), as well as nuclear energy, aerospace, hazardous waste management, heavy construction, and healthcare.

2. "Medium" complexity operations: lighter manufacturing (such as electronics), assembly, transportation, cleaning operations, hospitality, and education.

3. "Light" complexity operations: retail, engineering, telecommunications, restaurants, public administration, and finance.

Table 6 shows the instructions provided to CBs in MD 5 for how to apply these factors when estimating audit time (International Accreditation Forum, 2019a).

IAF MD 10:2013, IAF Mandatory Document for Assessment of Certification Body Management of Competence in Accordance with ISO/IEC 17021: 2011. This mandatory document provides instructions to help ABs assess the competence of a CB and its certification personnel. Specifically, it helps them determine whether CBs meet the competence requirements of ISO/IEC 17021:2011 *(Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems)*. ISO/IEC 17021:2011 is an important document for both accreditors and certifiers of management systems, including OHSMS, and is described in greater detail below. IAF MD 10:2013 addresses one of several requirements in ISO/IEC 17021:2011, that of ensuring the CB is competent to operate and oversee a certification process and that its auditors are competent in all aspects of auditing. Thus, IAF MD 10:2013 requires ABs to determine whether CBs have:

- Defined their certification process and the intended results for each step of the process. This includes all stages such as application review, establishing the audit program, scheduling of audits, allocation of audit teams, auditing and reporting, report reviews and certification decisions, and maintenance of certification.
- Defined competence criteria for each step in the process.
- Defined competence criteria for audit program oversight processes, such as certification review, assurance of impartiality, and review of auditor competence.

[11] The initial certification audit of an ISO management system proceeds in two stages. At Stage 1, the objective is to determine the organization's readiness for the full Stage 2 audit. During Stage 1, the CB reviews the documented information for the management system, collects site-specific information, and talks with key personnel. Stage 1 audits are usually but not always conducted remotely. Information collected during Stage 1 is used to plan the Stage 2 onsite audit. Stage 2 involves further review of management system documents and records, site tours, interviews with management, supervisors, and workers. Stage 2 audits also feature formal opening and closing meetings (TRC The Registry Company, 2018).

- Developed and implemented processes to document and maintain records of its competence determination processes.

Table 6. Occupational Health and Safety Management Systems - Relationship Between Effective Number of Personnel, Complexity Category of OH&S Risk, and Audit Time (Initial Audit Only: Stage 1 + Stage 2)

Effective No. of Personnel	Audit Time, Stage 1 + Stage 2 (Days)			Effective No. of Personnel	Audit Time, Stage 1 + Stage 2 (Days)		
	High	Med	Low		High	Med	Low
1–5	3	2.5	2.5	626–875	17	13	10
6–10	3.5	3	3	876–1,175	19	15	11
11–15	4.5	3.5	3	1,176–1,550	20	16	12
16–25	5.5	4.5	3.5	1,551–2,025	21	17	12
26–45	7	5.5	4	2,026–2,675	23	18	13
46–65	8	6	4.5	2,676–3,450	25	19	14
66–85	9	7	5	3,451–4,350	27	20	15
86–125	11	8	5.5	4,351–5,450	28	21	16
126–175	12	9	6	5,451–6,800	30	23	17
176–275	13	10	7	6,801–8,500	32	25	18
276–425	15	11	8	8,501–10,700	34	27	20
426–625	16	12	9	>10,700	Follow progression above		

Note: IAF MD5 defines "effective number of personnel" as "[A]ll personnel involved within the scope of certification including those working on each shift. When included within the scope of certification, it shall also include non-permanent (e.g., contractors) and part time personnel."
(Source: International Accreditation Forum, 2019a)

IAF MD 10 also provides instructions for ABs to follow to ensure that CBs have defined the technical areas for which it provides certification services and defined competence criteria for each of those technical areas. These technical areas represent specific subject matter, such as quality, information technology, or occupational safety and health. Thus, if the CB intends to certify OHSMS in the construction industries, it must define the knowledge and skills required of personnel performing certification functions in that technical area. The CB must also demonstrate its process for evaluating and ensuring the initial and continued competence of certification personnel in these technical areas, and in all stages of the audit process. In doing so, the CB may consider such personnel's prior work history and record of achieving intended results, but may not rely solely on such past experience (International Accreditation Forum, 2013).

IAF MD 15:2014, IAF Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance. This document identifies basic performance indicators that ABs are required to collect from CBs, monitor, and report on. The indicators include the number of valid certificates in place, number of auditors, number of transfers accepted (e.g., clients transitioning from one CB to another), number of overdue audits, and number of auditor-days delivered. The intent is for the AB to be able to evaluate, in part based on these data, that the CB has sufficient resources to manage the audits it is taking on (International Accreditation Forum, 2014).

IAF MD 17:2019, Witnessing Activities for the Accreditation of Management Systems Certification Bodies. MD 17 guides ABs in establishing programs to monitor the conduct of CBs through "witnessing," the onsite observation of audit activities.

Witnessing is used to verify the CB is following its defined programs and procedures and is demonstrating competence within the scope of its accreditation. CBs are required to inform clients of the potential for the AB to observe during the audit and include this disclosure in certification contract agreements. A client's refusal to accept a witnessed audit must be justified and accepted by both the CB and AB; insufficient justification may be grounds for withdrawal of the client's existing certificate.

ABs are instructed to select and schedule audits to be witnessed based on factors including:

- The CB's performance.
- The client's process complexity or legal landscape (which could challenge the competence of the CB).
- Feedback from interested parties including complaints about certified organizations.
- Results of the CB's internal audits.
- Changes in CB work patterns (e.g., growth of work within a new area).
- Previous witnessing activities.

Other factors could include:

- Number of certificates issued.
- Number of auditors.
- Different auditors.
- Whether auditors are internal staff or an external resource.
- Type of audit (initial/surveillance/recertification).
- Complex clients.
- Combined and/or integrated audits.
- Multi-site audits.
- Countries where audits in the certification process are performed.
- Complaints.
- Customer surveys.
- Interested parties' and regulators' requests.
- Technical clusters already assessed.
- Experience from other witnessed audits of the CB.

Before the audit, the AB must obtain the CB's audit plan, any previous audit reports, audit team competence records, and justification of the audit time. The AB, in turn, shall choose an assessment team for the audit and inform the CB of the team composition. Members of the AB witnessing team operate in strict "overserve only" mode and must not question or provide opinions or feedback to either the CB or the client during the audit. The witness team must also treat any information collected or observed during the audit as confidential. Normally, witnessing extends to the full onsite audit.

Following the audit, the AB witness team provides feedback to the CB audit team and communicates any findings or nonconformities. The witness team also provides a written report, which shall include comments on audit planning, selection and competence of the audit team, effectiveness of auditing methods, the CB's findings and audit conclusions, and a determination of whether the CB's written audit report accurately reflects the audit findings and conclusions.

Witnessing is done on a sampling basis, and IAF MD 17:2019 provides ABs with instructions on how to ensure their witnessing program is representative of all CBs and the technical "cluster" covered by those CBs. Technical clusters are defined for each management system scheme (quality, environmental, occupational health and safety). For example, for OHSAS 45001:2018 the "Food" technical cluster includes organizations that fall within the economic sectors "Food products, beverages and tobacco" or "Hotels and restaurants." Likewise, the "Supply" technical cluster includes organizations in electric, gas or water supply.

Generally, the AB is required to perform one witnessing activity within each technical cluster of the CB's accreditation. For an initial accreditation, this must occur within the accreditation cycle. After that, full sampling of all technical clusters must occur over two successive cycles (International Accreditation Forum, 2019b). Thus, if a CB is seeking accreditation for ISO 45001:2018 in three technical clusters, the AB is required to conduct witnessing of audits within each cluster to support initial accreditation, then every two years to support ongoing accreditation.

IAF MD 17:2019 goes further by defining "critical codes" for each technical cluster. Clusters assigned a critical code are technical areas that require the auditor to have more competency (e.g., due to complexity or processes), caution (e.g., due to risk of nonconformance or a high degree of regulation), or diligence (e.g., due to the personal behaviors or characteristics required to assess conformance). For example, the "Construction" technical cluster includes both construction (IAF Code 28) and engineering services (IAF Code 34). Within this, IAF Code 28 is assigned a critical code, meaning that for organizations with both construction and engineering services activities, the construction activities would be a higher priority for witnessing. The critical code designations also influence the sampling requirements within each technical cluster. For example, the "Mechanical" technical cluster includes the following industries: Fabricated metal products (IAF Code 17), Machinery and equipment (IAF code 18), Electrical and optical equipment (IAF Code 19), Shipbuilding (IAF Code 20), Aerospace (IAF Code 21), and Other transport equipment (IAF Code 22). Of these, Shipbuilding (IAF Code 20) and Aerospace (IAF Code 21) are assigned critical codes. If the CB witnesses a satisfactory certification audit within these two critical code areas, accreditation can be extended to all non-critical IAF code industries within the technical cluster without further witnessing.

IAF MD 20:2016, Generic Competence for AB Assessors: Application to ISO/IEC 17011. This document defines the competency requirements for AB "assessors" who review and assess CBs against an accreditation standard by reviewing documents, conducting onsite visits, or observing CB activities (e.g., witnessed audits). MD 20 requires ABs to establish competency requirements for assessors and establish procedures for selecting, training, and approving assessors. The competency requirements include both task-based competencies (planning and scheduling witnessing activities, interviewing, communicating findings and observations, reporting) as well as professional competencies (leadership, organizational, behavioral) (International Accreditation Forum, 2016a).

IAF MD 21:2018, Requirements for the Migration to ISO 45001:2018 from OHSAS 18001:2007. MD 21: 2018 provides instructions to ABs and CBs on the process for migrating existing clients with OHSAS 18001:2007 certificates to the more recent ISO 45001:2018 standard. OHSAS 18001 was first published in 1999, and its adoption grew until it became the de facto global OHSMS standard. In 2013, however, a process began to develop an ISO standard for OHSMS, resulting in the publication in 2018 of ISO 45001:2018. The OHSAS Project Group, developers of OHSAS 18001, have fully endorsed ISO 45001:2018 and agreed to "withdraw" OHSAS 18001:2007. This led to the need for a process to migrate organizations holding OHSAS 18001:2007 certificates to the ISO 45001:2018 standard. IAF, ISO, and the

OHSAS Project Group agreed to a three-year migration period. The migration period was extended to September 21, 2021, due the impact of COVID-19 on face-to-face auditing.[12]

MD 21:2018 requires ABs to develop a migration program, provide training to audit teams, and focus on differences between OHSAS 18001:2007 and ISO 45001:2018 during witnessed activities. It instructs CBs to develop migration plans that cover communication of the process to customers, training and verification of auditors, procedures for verifying ongoing conformity to OHSAS 18001:2007 during migration, and the actions they will take if any customer fails to complete migration within the three-year, six month extended period (e.g., what level of audit will be required for recertification). CBs can conduct migration activities during routine surveillance audits, recertification audits, or special audits. When migration is verified during surveillance or recertification audits, the audit duration shall be adjusted to allow enough time to cover changes between the two standards (at least one additional day).

IAF MD 22:2019, Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS). ISO/IEC 17021 provides a comprehensive framework for establishing, operating, monitoring, and improving a management system certification program. IAF MD 22:2019 provides instructions on how to consistently apply ISO/IEC 17021 to the certification of OHSMS. IAF MD 22 was initially prepared to support OHSAS 18001:2007 certification activities, but the current version, IAF MD 22:2019, states that it also applies to ISO 45001:2018 and other OHSMS standards.

Prohibited activities

The document begins by identifying certain OHS services that are considered "consulting" services. Under ISO/IEC 17021, CBs are prohibited from providing consulting services to organizations:

> *"5.2.5 The certification body and any part of the same legal entity and any entity under the organizational control of the certification body … shall not offer or provide management system consultancy."*
>
> **(International Organization for Standardization, 2015).**

IAF MD 22:2019 clarifies that "management system consultancy" shall include:

- Serving as occupational health and safety coordinator.
- Safety reporting.
- Performing risk assessments.
- Performing occupational health and safety inspections and internal audits.
- Communication with regulatory authorities on behalf of the client.
- Assistance in developing an organization's OHSMS.
- Accident and incident investigation.

Notification

Clause 8 of IAF MD 22:2018 requires any certified organization to inform its CB, without delay, of "the occurrence of a serious incident or breach or regulation necessitating the involvement of the competent regulatory authority."

[12] https://iaffaq.com/category/ohsms/

Pre-certification

To the information that ISO/IEC 17021 requires CBs to collect from client organizations before certification, IAF MD 22:2019 adds the following:

- The key hazards and OHS risks associated with processes.
- Hazardous materials used in the processes.
- Relevant legal obligations related to OHS.
- Details of personnel working on, as well as working away from, the premises.

Audit time

IAF MD 5:2019, Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems (above) provides instructions on how to determine the audit time for OHSMS certification activities. IAF MD 22:2019 reproduces much of these requirements and adds requirements for organizations whose employees provide services at other organizations' worksites. This is important, as onsite contracting is increasingly common, and many organizations that contract with such businesses have an interest in the OHS policies and performance of such businesses:

> *"In determining the time to be spent for audit, the CAB shall consider to audit periodically any organization site where these employees work. Whether all sites shall be audited will depend on various factors such as OH&S risks associated with the activities therein performed, contract agreements, being certified by another accredited CAB, internal audit system, statistics on accidents and near misses. The justification for such decision shall be recorded."*
>
> **(International Accreditation Forum, 2019c).**

Compliance assurance

All management system standards require the organization seeking certification to develop, implement, and maintain a process (or processes) for evaluating compliance with legal and other requirements. ISO/IEC 17021 requires the certification audit to include a "determination of the ability of the management system to ensure the client meets applicable statutory, regulatory and contractual requirements" but clarifies that "[a] management system certification audit is not a compliance audit" (International Organization for Standardization, 2015). This raises the question of how the CB confirms the organization's conformance with the compliance-related sections of the standard. IAF MD 22:2019 devotes Appendix C to this topic for audits of the OHSMS. Appendix C emphasizes several points, including:

- The CB shall not certify, or continue to certify, any organization that fails to demonstrate its commitment to legal compliance.[13]
- Deliberate or consistent failure to achieve legal compliance shall be evidence of a serious nonconformance with the policy requirement to achieve legal compliance. Any such

[13] It is notable that MD22:2018 limits discussion to "legal compliance." ISO 45001:2018 (and ISO/IEC 17021:2015 more broadly) address both legal and "other" requirements, with "other" requirements defined as "requirements … that an organization … chooses to comply with." Examples of such requirements could include parent company policies, collective bargaining agreements, voluntary industry codes of conduct, contractual conditions, etc.

organization shall not be granted certification and shall lead to suspension or withdrawal of an existing certification.

- The CB must verify the management of legal compliance based on the demonstrated implementation of the system and not rely only on planned or expected results. For example, the existence of written programs designed to address compliance with specific legal requirements that are not fully implemented shall not be sufficient.[14]
- The organization must demonstrate its ability to maintain legal compliance, in part through its own evaluation of compliance prior to the certification audit. Thus, part of the certification audit shall include a review of the organization's own compliance evaluation.
- If the organization is not in legal compliance, it needs to be able to demonstrate a plan is in place to achieve full compliance by a specific date and that such plan is given high priority. Where possible, such plans shall be approved by the regulator.
- The CB shall maintain a procedure describing the actions it will take if it identifies a noncompliance with a relevant regulatory requirement. This will include a requirement that any such noncompliance be communicated immediately to the organization being audited.

Selection of personnel to interview

ISO/IEC 17021:2015 stresses the value of interviews as a tool for evaluating the management system but does not identify specific individuals or positions to target for interviews. IAF MD 22:2019, however, includes requirements for CBs to interview the following individuals:

- Management with legal responsibility for OHS.
- Employees' representative(s) with responsibility for OHS.
- Personnel responsible for monitoring employees' health, for example doctors, nurses, or other occupational health professionals.
- Managers and permanent and temporary employees.

The document also recommends, but does not require, CBs to interview:

- Managers and employees performing activities related to the prevention of OHS risks.
- Contractors' management and employees.

Maintaining certification

IAF MD 22:2019 specifies that a serious incident or violation of an applicable OHS law or regulation may warrant a special audit. Such an audit shall focus on determining whether the incident represents a failure of the OHSMS. Information resulting from such an investigation, from incidents reported by the organization to the certifier (see above), or from findings made by the regulatory authority, may provide grounds for actions taken by the CB. These may include suspension or withdrawal of a certification. CBs must include this provision in any contractual agreement.

[14] Examples of compliance "programs" in the U.S. might include a confined space program to prevent exposure to hazards from contaminated or oxygen-poor atmospheres (as required by 29 CFR 1910.146), or a lockout-tagout program to prevent exposure to hazards from energized equipment (as required by 29 CFR 1910.147).

Scope of accreditation

IAF MD 22:2019 includes an appendix (Appendix D) outlining the process for determining the scope of accreditation under ISO 45001:2018. CBs must seek accreditation under one or more of these scopes and may only carry out certification within the scope(s) for which they are accredited. For ISO 45001:2018, these scopes generally correspond to industry categories. To gain accreditation under each scope, the CB must demonstrate familiarity with, and knowledge of, the industry group and the OHS hazards that are common to them. CBs may expand their scopes as they acquire and can demonstrate expertise in additional industries. Table 7 lists these scopes along with the corresponding European Classification of Economic Activities (NACE) codes and the common OHS hazards encountered within each scope. Many CBs specialize in a single industry or a few related industries. Other CBs are accredited to very broad scope that includes many industries. Regardless, each CB providing OHSMS certification must demonstrate its knowledge of the industry groups it serves.

Table 7. Scope of Accreditation for OHSMS Certification Bodies

No.	Description of Economic Sector/Activity	NACE Division/Group/Class (Rev. 2)	Examples of Common OH&S Hazards*
1	Agriculture, forestry and fishing	01, 02, 03	Exposure to pesticide, biological and chemical hazards, farm mobile vehicles and equipment, machinery, work at height, manual handling, respiratory disease, zoonoses, noise, repetitive stress, etc.
2	Mining and quarrying	05, 06, 07, 08, 09	Rock fall, fire, explosion, mobile vehicles, machinery, falls from height, entrapment and electrocution, noise, vibration, exposure to radon, crystalline silica exposure, coal dust, hazardous chemicals, working in confined spaces, etc.
3	Food products, beverages and tobacco	10, 11, 12	Exposure to pesticide, biologic and chemical hazards, mobile vehicles and equipment, tools, machinery, cold areas (freezer), hot media, repetitive stress, etc.
4	Textiles and textile products	13, 14	Machinery and equipment, exposure to dyes and chemicals, wool and flock dust, fire, explosion, weight loading and unloading, noise, etc.
5	Leather and leather products	15	Exposure to chromium and other hazardous chemicals, machinery, pressure equipment, unsafe workplace, weight loading and unloading, noise, etc.
6	Wood and wood products	16	Exposure to hazardous chemicals, wood dust, various machinery and tools, fire, explosion, etc.
7	Pulp, paper and paper products	17	Exposure to hazardous chemicals, plant and pressure equipment, machinery, fire, explosion, unsafe workplace (heat radiation, dust), noise, etc.
8	Publishing companies	58.1, 59.2	Video display terminal (VDT), body posture, lighting, repetitive stress, etc.
9	Printing companies	18	Exposure to hazardous chemicals, machinery, noise
10	Manufacture of coke and refined petroleum products	19	Exposure to hazardous chemicals, machinery, plant and equipment, pressure equipment, fire, explosion, working in confined spaces, working at height, noise, explosion, coal dust, etc.

Table 7. Scope of Accreditation for OHSMS Certification Bodies

No.	Description of Economic Sector/Activity	NACE Division/Group/Class (Rev. 2)	Examples of Common OH&S Hazards*
11	Nuclear fuel	24.46, 20.13 (only in scope of radioactive material)	Exposure to radiation/radioactivity, exposure to hazardous chemicals, plant and equipment, etc.
12	Chemicals, chemical products and fibers	20 (except scope of radioactive material)	Exposure to hazardous chemicals, machinery, plant and equipment, pressure equipment, fire, explosion, working in confined spaces, working at height, noise, explosion, dust, etc.
13	Pharmaceuticals	21	Exposure to biological and chemical hazards, exposure to radiations, plant and pressure equipment, fire, explosion, working in confined spaces, etc.
14	Rubber and plastic products	22	Machinery, plant and pressure equipment, exposure to chemical hazards, fire, explosion, noise, etc.
15	Non-metallic mineral products	23, except 23.5 and 23.6	Machinery, plant and pressure equipment, electricity, fire, explosion, hazardous chemicals, noise, paint and coatings, etc.
16	Concrete, cement, lime, plaster etc.	23.5, 23.6	Ground works and excavations work at height, mobile plant and machinery, manual handling, noise, vibration, dust, electricity, fire, explosion, etc.
17	Basic metals and fabricated metal products	24 except 24.46, 25 except 25.4, 33.11	Machinery, plant and equipment, pressure equipment, fire, explosion, hazardous chemicals, working at height, noise, paint and coatings, radiation, etc.
18	Machinery and equipment	25.4, 28, 30.4, 33.12, 33.2	Machinery, plant and equipment, pressure equipment, hazardous chemicals, paint and coatings, noise, vibration, manual handling, fire, explosion, etc.
19	Electrical and optical equipment	26, 27, 33.13, 33.14, 95.1	Machinery, plant and equipment, pressure equipment, electricity, radiation, hazardous chemicals, noise, vibration, manual handling, etc.
20	Shipbuilding	30.1, 33.15	Machinery, plant and equipment, pressure equipment, hazardous chemicals, noise, vibration, manual handling, working at height, working in confined spaces, fire, explosion , radiation, paint and coatings, etc.
21	Aerospace	30.3, 33.16	Machinery, plant and equipment, pressure equipment, hazardous chemicals, paint and coatings, noise, vibration, radiation, manual handling, fire, explosion, etc.
22	Other transport equipment	29, 30.2, 30.9, 33.17	Machinery, plant and equipment, pressure equipment, hazardous chemicals, paint and coatings, paint and coatings, noise, vibration, manual handling, etc.
23	Manufacturing not elsewhere classified	31, 32, 33.19	Machinery, plant and equipment, pressure equipment, hazardous chemicals, noise, vibration, manual handling, paint and coatings etc.

Table 7. Scope of Accreditation for OHSMS Certification Bodies

No.	Description of Economic Sector/Activity	NACE Division/Group/Class (Rev. 2)	Examples of Common OH&S Hazards*
24	Recycling	38.3	Traffic, machinery, exposure to chemical and biological hazards, slips, trips, falls, radiation, repetitive stress, noise, fire, explosion, etc.
25	Electricity supply	35.1	Plant and equipment, electricity, exposure to electro-magnetic fields, machinery, hazardous chemicals, noise, vibration, work at height, etc.
26	Gas supply	35.2	Pressure equipment, machinery, fire and explosion associated with loss of containment of gas, toxicity, noise, vibration, work in confined spaces, work at height, etc.
27	Water supply	35.3, 36	Plant and equipment, machinery, exposure to chemical hazards, noise, vibration, work at height, work in confined spaces, *Legionella,* etc.
28	Construction	41, 42, 43	Ground works and excavations, work at height, mobile equipment accidents, falls from height, tower cranes, mobile plant and machinery, temporary works, manual handling, noise, vibration, dust, paint and coatings, electricity (overhead electric lines and underground cables), fire, etc.
29	Wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods	45, 46, 47, 95.2	Machinery, tools, hazardous chemicals, noise, vibration, manual handling, chemicals, etc.
30	Hotels and restaurants	55, 56	Slips and trips, hot objects, cold areas (freezers), sharp objects, chemicals, biological waste, *Legionella,* etc.
31	Transport, storage and communication	49, 50, 51, 52, 53, 61	Traffic, speed, overturning, crash, being hit by a moving vehicle, falls from vehicles, manual handling, slips and trips
32	Financial intermediation; real estate; renting	64, 65, 66, 68, 77	VDT, body posture, lighting, repetitive stress, etc.
33	Information technology	58.2, 62, 63.1	VDT, body posture, lighting, repetitive stress, etc.
34	Engineering services	71, 72, 74 except 74.2 and 74.3	VDT, wide variation in function of the specific service
35	Other services	69, 70, 73, 74.2, 74.3, 78, 80, 81, 82	Wide variation in function of the specific service
36	Public administration	84	VDT, body posture, lighting, ergonomics, wide variation, etc.
37	Education	85	VDT, lighting, ergonomics, stress, noise, etc.
38	Health and social work	75, 86, 87, 88	Exposure to biological hazards, radioactivity, disease contamination, weight handling, etc.
39	Other social services	37, 38.1, 38.2, 39, 59.1, 60, 63.9, 79, 90, 91, 92, 93, 94, 96	Machinery, exposure to chemical and biological hazards, slips, trips, falls, repetitive stress, noise, wide variation in function of the specific service

NACE = European Classification of Economic Activities code.
* Examples of common hazards are not supposed to be included in the scope of accreditation.
(Source: International Accreditation Forum, 2018)

2.4. U.S. Participation in the IAF

Most countries around the world operate a single, national AB, and most of these are government agencies. These national bodies normally represent their country as members of the IAF. In the United States, however, ABs are private organizations, not government agencies. ANAB (the ANSI National Accreditation Board) is the most prominent U.S. management system AB today. ANAB is a wholly owned, nonprofit subsidiary of ANSI, the American National Standards Institute. ANAB was formed in 2005 when ANSI took full ownership of the former Registration Accreditation Board (RAB), which it had operated in partnership with the American Society for Quality since 1991. In 1998, RAB was one of the original 13 signatories of the IAF MLA. Thus, ANAB (formerly RAB) is the longest-standing U.S. member of IAF. As of June 2020, the IAF membership website does not include ISO 45001:2018 among the Level 5 scopes covered by the current ANAB MLA (this may be an oversight on IAF's behalf). A search of the ANAB website indicates it has accredited 26 CBs for ISO 45001:2018. Of these, 16 are in the United States.[15] More information about ANAB is presented in Section 4 below.

In 2010, the International Accreditation Service (IAS), a U.S.-based accreditor, become the second management system AB to join IAF. IAS is a subsidiary of the International Code Council (ICC), a nonprofit that develops International Codes used in the design and construction industry. The IAF membership website indicates that ISO 45001:2018 was added to the scope of the IAS MLA in May of 2020. A search of the IAS website indicates it has accredited 48 CBs for ISO 45001:2018. Of these, six are in the U.S.[16]

Two other U.S. organizations are also IAF members and MLA signatories. Neither of these, however, include management systems within the scope of their MLA. The American Association for Laboratory Accreditation (A2LA) accredits testing and calibration laboratories.[17] The International Organic Accreditation Service (IOAS) accredits organizations that certify producers making claims in the areas of organic and sustainable agriculture, environmental standards, social justice, and fair trade (International Organic Accreditation Service Inc., 2019).

2.5. The InterAmerican Accreditation Cooperation

As noted above in Section 2.2, the IAF accepts ABs as members following a peer evaluation. These peer evaluations serve to verify the AB has the policies and procedures in place required for IAF membership and by the IAF MLA. IAF relies on regional accreditation organizations to conduct these evaluations. IAAC, based in Mexico City, is one of several of these. IAAC conducts evaluations across North, Central, and South America. IAAC operates in a manner similar to IAF, in that it accepts members for the purpose of mutually recognizing accreditations granted by other members. IAAC does this through its own MLA.[18]

[15] https://anabdirectory.remoteauditor.com/
[16] https://www.iasonline.org/search-accredited-organizations-2/
[17] https://www.a2la.org/about
[18] As noted earlier, there are two ABs operating in the U.S., ANAB and IAS. ANAB is a member of IACC and a signatory of its MLA; thus, it is assumed that IACC conducts the peer reviews of ANAB. IAS is a member of the Asia-Pacific Accreditation Corporation and signatory of its MLA; this it is assumed that IACC conducts the peer reviews of IAS.

IAAC operates as a nonprofit corporation with an Executive Committee, a Secretariat, and many committees and subcommittees. The Peer Evaluators Management Subcommittee, a subcommittee of the MLA Committee, sets policy and procedures for the peer evaluation process. The MLA Group, also a subcommittee of the MLA Committee, provides guidance and oversight to the Peer Evaluators Management Subcommittee and has final approval on new members. IAAC has published several documents and templates to support peer evaluations, and provides training to new and experienced peer evaluators.

IAAC MD 002 *(Policies and Procedures for a Multi-Lateral Recognition Arrangement Among Accreditation Bodies)* (Interamerican Accreditation Cooperation, 2020) outlines the procedure for peer evaluations of ABs. Behrens and Wloka (2008) have more fully documented this process and the following discussion draws from their description. For a new member, the peer evaluation begins with the organization completing and submitting an application for IAAC membership. As with IAF membership, organizations apply for accreditation within specific areas of activity, under which specific standards fall (see Table 1 above). Within 90 days of acceptance, IAAC appoints a team and team leader for the evaluation and informs the applicant of the team composition. The team receives the applicant's membership information and may request additional documents from the applicant. Based on this document review, the team leader may then recommend a preliminary visit to determine whether the applicant is ready for a full evaluation. If the MLA Group approves a preliminary visit, the team leader coordinates logistics for the visit and prepares a short, written report following the visit, noting any corrective actions that may be needed. Once the applicant has submitted documentation demonstrating it has taken effective corrective actions, the peer evaluation team prepares for a full evaluation. The same team leader who oversaw the preliminary visit normally continues in that role for the full evaluation.

For the full evaluation, the MLA authorizes the evaluation team leader to set the duration for the review, based on the nature of the applicant, the scope of the evaluation, and other factors. Applicants are responsible for the travel, accommodations, and per diem expenses of the peer evaluation team. Generally, evaluations take less than seven days to complete.[19] An important component of the evaluation is witnessing, in which one or more evaluation team members observe the applicant conduct an assessment of a CB. The evaluation team determines the number and type of assessments to witness, factoring in the standards the organization is seeking accreditation for, the size of the market, new and complex "fields" (industries), and other factors. Evaluation teams are advised to witness an initial assessment or a reassessment of a CB or two onsite assessment activities for every Level 3 scope.

IAAC provides evaluation teams a number of tools to support the evaluation. Among these are:

- A list of documents the applicant is required to submit as part of its application.
- An evaluation team checklist used during document review.
- An evaluation team program template used to assign evaluators to check applicant programs against different requirements in ISO/IEC 17011 as well as IAF and IAAC requirements.
- Performance review forms for evaluation team leaders and team members.

[19] An IACC administrative document used to calculate the cost of peer evaluation states that "peer evaluations can last approximately six days, plus the travel days." (Interamerican Accreditation Cooperation, 2019).

IAAC evaluation teams also use IAF templates, such as the IAF/ILAC[20] report template for reporting on the results of a peer evaluation (International Accreditation Forum & International Laboratory Accreditation Forum, 2017). This template prescribes the elements each report should cover, depending on the type of evaluation. The most important part of the report is the findings section: here the evaluation team presents its determination of whether the applicant conforms to the various requirements of an applicable standard (e.g., ISO/IEC 17021), the organization's own management system, or requirements of the MLA.

A peer evaluation finding may be classified as a nonconformity, concern, or comment:

- For a **nonconformity,** the applicant is required to respond by taking corrective action and provide the evaluation team with evidence of effective implementation of such actions. The nonconformity is considered closed when the evaluation team accepts the evidence of effective implementation.
- When the evaluation team flags a **concern,** the applicant is expected to respond with an appropriate action plan and timetable for implementation. The concern is closed once the evaluation team accepts the plan and has confirmed the applicant has begun implementing the plan.
- When the evaluation team makes a **comment,** the applicant is required to respond to the comment. The comment is considered closed when the response is received.

Final decisions on whether to grant an applicant MLA signatory status are made by the MLA Group following review of the peer evaluation team's final report. The MLA Group may send comments or questions to the team leader. Once these are addressed, the MLA Group votes to determine what action to take. Actions may include approval without conditions, approval with conditions, deferred approval pending satisfactory evidence of corrective action, or disapproval with a new evaluation required.

MLA signatory status is valid for at most four years. IAAC MD 002 *(Policies and Procedures for a Multi-Lateral Recognition Arrangement Among Accreditation Bodies)* provides grounds for suspension and, if necessary, withdrawal of MLA signatory status by the MLA Group. It also provides for periodic monitoring of MLA signatories, as well as re-evaluations (Interamerican Accreditation Cooperation, 2020). The re-evaluation process is similar to that used for initial evaluations. An MLA signatory may also be re-evaluated any time it applies for an extension of its scope to include a new Level 3 activity (see Table 1). This triggers a full evaluation of all MLA requirements, similar to an initial evaluation. Extensions of management system sub-scope (Levels 4 and 5) do not require evaluation. Instead, the AB must submit a self-declaration using IAF MLA MC 28, *MLA Declaration for Sub-Scope Extensions (Region).* The MLA Group reviews and approves or denies the extension based on this submission.[21]

[20] ILAC is the International Laboratory Accreditation Corporation, an international organization for accreditation bodies operating in accordance with ISO/IEC 17011:2017 and involved in the assessment and accreditation of calibration laboratories and testing laboratories (using ISO/IEC 17025:2017), medical testing laboratories (using ISO 15189:2004) and inspection bodies (using ISO/IEC 17020:2012).

[21] Since ISO 45001 is considered a level 5 sub-scope (see Table 1), we interpret it to mean an AB extending its scope to cover OHSMS would only need to fill out a form and send it to IACC/IAF.

3. ISO/IEC 17011

ISO/IEC 17011:2017 sets out the requirements for assuring the "competence, consistent operation and impartiality" of ABs engaged in the assessment and accreditation of CBs. Activities covered by accreditation include, but are not limited to, "testing, calibration, inspection, certification of management systems, persons, products and services, provision of proficiency testing, production of reference materials, validation and verification" (International Organization for Standardization, 2017). ISO/IEC 17011 was originally published in 2004 and most recently updated in 2017.

ISO/IEC 17011 begins by setting out the **general requirements** for ABs. These are found in Section 4 of the standard. They include a requirement for each AB to have a legally enforceable accreditation agreement in place with each CB it accredits. The agreement requires the CB to fulfill the requirements of accreditation, provide access to CB personnel and documents, arrange for the AB to witness CB activities if requested, and not claim accreditation beyond the scope for which it has been accredited. As part of this, the CB is in turn required to have a legally enforceable arrangement with its clients, requiring that they provide access to ABs (if requested) for the purpose of assessing the CB's performance when conducting assessment activities. These general requirements also cover proper use of accreditation status claims and accreditation symbols or logos by CBs. There is also an extensive set of requirements devoted to ensuring the impartiality of the accreditation process. This includes a prohibition on ABs providing consultancy services.

The next section of ISO/IEC 17011 (Section 5) deals with **structural requirements.** The overall focus of this section is on ensuring the impartiality of each AB. Specific requirements cover documenting the AB's organizational structure and the duties, responsibilities, and authorities of top management and others responsible for accreditation decisions, as well as identification of top management including those responsible for various aspects of accreditation and operation of the AB.

Regarding **resource requirements,** Section 6 of ISO/IEC 17011 specifies that the AB shall have a process for assessing and documenting the competence of personnel, maintain personnel records, not outsource accreditation decisions, and take responsibility for all (non-accreditation) activities that are outsourced. Each AB is required to maintain a documented process for "determining and documenting the competence criteria for personnel involved in the management and performance of assessments and other accreditation activities." Annex A of ISO/IEC 17011, reproduced below in Table 8, summarizes the competence requirements applicable to the different accreditation activities. ABs must also maintain processes for evaluating the competence and performance of personnel involved in assessment activities on both an initial and ongoing basis, and for selecting, training, and formally authorizing assessors. Assessor monitoring programs must include a combination of onsite evaluation; review of assessment reports; and feedback from personnel, conformity assessment bodies, or other interested parties. Every assessor must be observed while conducting or participating in an assessment at regular intervals, but at least every three years.

Each AB must maintain access to enough qualified assessors and other personnel to support all of its assessment activities across all schemes (e.g., OHSMS) for which it is accredited itself. Assessors and other personnel must be provided with a written set of procedures outlining the assessment process. ABs must keep records of personnel qualifications, training, competence, and results of performance monitoring. ABs are expected to conduct all assessments themselves. Before outsourcing any assessment activities, the AB must document the conditions under which outsourcing may occur and the procedures it will follow, and must monitor any outsourced activities. All personnel with responsibility

for accreditation decisions must be employed by the AB itself; no outsourcing of such decisions is permitted.

Table 8. Table of Knowledge and Skills

Knowledge and Skills	Accreditation Activities				
	Application Review, Including Selection of Team Members	Document Review	Assessment	Reviewing Assessment Reports and Making Accreditation Decisions	Management of Accreditation Schemes
Knowledge of accreditation body's rules and processes	✓	✓	✓	✓	✓
Knowledge of assessment principles, practices and techniques		✓	✓	✓	
Knowledge of general management system principles and tools		✓	✓	✓	
Communication skills appropriate to all levels within the conformity assessment body			✓		
Note-taking and report-writing skills		✓	✓		
Opening and closing meeting skills			✓		
Interviewing skills			✓		
Assessment-management skills			✓		
Knowledge of accreditation and accreditation scheme requirements and relevant guidance and application documents	✓	✓	✓	✓	✓

The required knowledge and skills can be provided collectively by a group of persons involved in the specified accreditation activity.
(Source: International Organization for Standardization, 2017, Annex A).

The bulk of ISO/IEC 17011 (Section 7) describes **process requirements** for accrediting CBs. These begin with each AB establishing a process for CBs to follow when applying for accreditation. The AB must then make a determination of its ability to conduct the assessment based on the resource requirements, including the competence and availability of assessors, and notify the CB of its assessment in a timely manner. To prepare for an accreditation assessment, the AB must choose a team of qualified assessors with clearly defined assignments, ensure that they have a representative sample of the CB's conformity assessment activities to evaluate, develop an assessment plan, and review all documentation provided by the CB. When choosing which activities to assess, the AB must consider the risk associated with the activities, as well as the locations and personnel covered by the scope of accreditation.

The AB's assessment of the CB begins with an onsite or remote opening meeting. The AB then conducts the assessment based on the assessment plan, reviews all relevant information, sets a timeframe to correct any nonconformities affected, and requires a root cause analysis for any nonconformities. Each assessment concludes with a closing meeting during which the assessment team reports on the findings made during the assessment, including details of any nonconformities and the basis for such findings. This is followed by a written report delivered in a timely manner. The assessment team then monitors

the response of the CB to its findings, and determines whether the response has been sufficient and appropriate.

Each AB must maintain a documented procedure outlining its accreditation decision-making process. The decision about whether or not to grant accreditation to the CB shall be made by competent persons or committees not involved in the assessment themselves, and they must evaluate all available information (without undue delay) before making the decision. This applies whether the assessment is for an initial accreditation, accreditation renewal, scope extension or reduction, or accreditation suspension or withdrawal.

Once a decision is made, the AB shall provide the CB with a statement of conformity that refers to a standard (e.g., ISO/IEC 17021) and industry sector(s) (where appropriate), along with the effective date.

Each accreditation must be reassessed within five years, including an assessment of a sample of the scope of accreditation at least every two years, ideally onsite. The accreditation can be suspended, withdrawn, or reduced at any time if the CB is not fulfilling the requirements or if there is evidence of fraud.

The final process requirements deal with the AB's procedure for handling complaints against the CB and appeals about accreditation decisions. Each AB must have a procedure for receiving, evaluating, and responding to complaints. When a complaint is against a CB, the AB must give the CB an opportunity to respond and address the complaint. CBs, in turn, may appeal any decision made by an AB. The AB is required to maintain a documented appeals process, gather, and verify relevant information related to the appeal, and communicate the status of the appeal and the final decision to each appellant.

The next section of ISO/IEC 17011 (Section 8) deals with **information requirements.** These include having a process for keeping information obtained during assessments confidential, and making information about the AB process and a list of accredited CBs available to the public (e.g., on a website).

The final section of ISO/IEC 17011 (Section 9) describes **management system requirements** for the AB. These include establishing and maintaining a management system that can meet the requirements of ISO/IEC 17011, is appropriate to the type and volume of work, includes a document control system, includes procedures governing the maintenance and disposition of records, includes a process for identifying and correcting nonconformities in its own operations, includes internal audits to ensure compliance with ISO/IEC 17011, and includes periodic management reviews.

4. THE ANSI NATIONAL ACCREDITION BOARD

As noted in Section 2.4 above, ANAB is the most prominent U.S. AB and a founding member of the IAF. Based in Milwaukee, Wisconsin, ANAB describes itself as "the largest multi-disciplinary accreditation body in the western hemisphere, with more than 2,500 organizations accredited in approximately 80 countries" (ANAB, 2020a). ANAB provides accreditation across many areas in addition to management systems, including calibration and testing laboratories, inspection bodies, product CBs, forensic service providers, validation and verification bodies, proficiency testing providers, reference material producers, and credentialing programs (ANAB, 2020a). ANAB does not develop standards, but it is a wholly owned subsidiary of one of the largest U.S. standards-setting organizations, ANSI. ANSI is also the official organization representing the U.S. at ISO. ANAB revenues come from the fees it charges for the accreditation services it provides.

4.1. ANAB Documents

ANAB operates in accordance with the requirements of ISO/IEC 17011 *(Conformity Assessment—General Requirements for ABs Accrediting Conformity Assessment Bodies)* as well as key IAF mandatory documents such as IAF A5 *(Multi-lateral Mutual Recognition Arrangements: Application of ISO/IEC 17011)* and IAF MD 12 *(Assessment of Certification Activities for Cross Frontier Accreditation).* To demonstrate conformance, ANAB has itself developed documentation of the procedures it uses to manage its accreditation activities. Some of these essentially mirror ISO or IAF documents, while others are more specific to ANAB and to accreditation of OHSMS. The following sections describe several of these documents in more detail.

4.1.1. MA 5000 Management Systems Accreditation Manual

MA 5000 sets out ANAB's procedures for operating its management systems accreditation business. The target audience for the manual are CBs seeking accreditation (ANAB, 2020b). The manual begins by describing the accreditation application process. The applicant must first show conformance with some of the main ISO/IEC 17021 requirements and pay an initial application fee. After review, ANAB notifies the CB to proceed to the next step, which involves purchasing an application for a specific standard (e.g., ISO 45001:2018) and uploading the completed application. (Application fees are non-refundable and must be paid again if an applicant is denied accreditation but decides to re-submit an application.)

ANAB verifies it has the resources needed to assess the CB and publishes on its website a public notice of the application with a request for comments. The CB must agree to participate in assessment activities in a timely manner, such as responding to ANAB requests for information and arranging for office assessments or witnessed audits. If a CB is unable to achieve accreditation within one year of its application, ANAB may withdraw the CB's application. ANAB staff and assessors maintain accreditation information in an online portal, the ANAB Enterprise Quality Manager (EQM).[22] CBs applying for accreditation or renewing accreditation also upload information through EQM.

ANAB forms an assessment team and informs the CB of the team composition. Before any office assessment, the CB completes several ANAB forms: FM 5302 *(CB Key Processes),* FM 5303 *(CB Profile),* FM 5304 *(CB Structure),* and FM 5305 *(Assessment Program).* Prior to the office assessment, the CB must provide evidence it has completed at least one internal audit of its management system and one management review. The applicant CB must also submit at least one complete client file, documenting the entire audit process from application through certification decision.[23]

For witnessed audits, the ANAB assessment team (excluding technical experts) equals the size of the CB's audit team. CBs are required to include enforceable arrangements in certification contracts authorizing ANAB to witness their audit teams at client sites. If a client refuses an ANAB-witnessed audit, the CB is required to remove the ANAB accreditation from the client's certificate or withdraw the certificate. If the organization attempts to avoid an ANAB-witnessed audit by transferring to a different

[22] Accessible to ANAB and ANAB-Accredited CBs at https://anab.ansi.org/eqm-login.

[23] CBs that are not yet accredited by ANAB may issue certificates, but such certificates may not bear the ANAB logo until after the CB achieves ANAB accreditation. Non-ANAB certificates (and non-accredited certificates generally) are not automatically recognized and accepted because they are not issued under the auspices of the IAF MLA. A non-accredited certificate may be converted to an accredited one after the CB achieves accreditation; ANAB provides a process and guidance for doing so.

CB, the accepting CB will be prohibited from issuing an ANAB-accredited certificate to that organization. ANAB will also notify IAF member ABs of the refusal.

ANAB's witness team observes both Stage 1 and Stage 2 of the management system audit. The CB must provide ANAB a copy of its Stage 1 audit report or initial conclusions before commencing Stage 2. Upon completion of the Stage 2 audit, the ANAB assessment team prepares an assessment report on the witnessed activities. The report describes the assessment, documents any nonconformance reports (NCRs), issues any requests for further information (RFIs), highlights opportunities for improvement (OFIs), and makes recommendations from the assessment team. The CB must respond to an NCR with a root cause analysis and corrective action plan. An RFI requires the CB to provide ANAB with specific information, while OFIs do not require a response. The assessment report, NCRs, RFIs and OFIs are entered into EQM, as are the CB responses.

Assuming the assessment team determines the applicant's certification system meets all requirements (including those of ISO/IEC 17021), ANAB staff submit an accreditation package to the ANAB Management Systems Accreditation Council. The Council has access to all assessment reports and the CB responses, through EQM. Accreditation decisions are governed by ANAB PR 5500 *(Management Systems Accreditation Council Operating Procedure).* If the committee votes in favor of accreditation, ANAB staff inform the CB in writing. If accreditation is recommended with conditions, ANAB staff ensure the CB meets those conditions. If the committee votes against initial accreditation, ANAB staff inform the CB in writing of the basis for the determination and any next steps for the applicant. This can include an appeal of the decision.

The MA 5000 manual includes a set of procedures that CBs must follow to convert or issue any subsequent certificates that include the ANAB logo (i.e., ANAB-accredited certificates).

ANAB accreditations are valid for five years. ANAB monitors the performance of CBs following their initial accreditation by conducting office assessments within six months of initial accreditation or 12 months of the initial office assessment (whichever comes first) and every 12 months thereafter. ANAB also witnesses audits for each standard for which the CB is accredited, on an annual basis. ANAB may adjust its monitoring program at any time it has concerns about the CB's operation or activities. The manual lists several factors that may trigger increased monitoring: significant organizational changes, increased certification activity, multiple NCRs and/or complaints in a specific program or process, relationships that cause a real or perceived conflict of interest, or other conditions deemed appropriate.

ANAB provides public notification of applications for accreditation (including the subsequent withdrawal of an application) and the granting, renewal, suspension, and withdrawal of accreditations. ANAB maintains on its website a publicly available directory of ANAB-accredited CBs, lists of applicant and transitioned CBs, and information on suspensions and withdrawals of accreditation.

Suspension or withdrawal decisions are made by a three-member panel, appointed by the chair of the ANAB Management Systems Accreditation Council from among the Council's members. The panel first conducts a suspension or withdrawal hearing, which the CB may attend in person or via teleconference. ANAB staff provide the panel with the recommendation for suspension or withdrawal and relevant documentation to support the recommendation. The CB may submit documentation contesting or rebutting the suspension or withdrawal recommendation. Each party is granted time to present its position to the panel and to answer questions from the panel. After the hearing, the panel deliberates without further input from the CB or ANAB.

Suspensions or withdrawals may also be initiated voluntarily by any CB. Reasons for doing so vary, but may include the decision to discontinue certification for a specific standard, or an acquisition that creates a conflict of interest.

Any CB that has its accreditation suspended must continue to conduct surveillance audits and recertification audits, and may conduct initial certification audits but may not issue ANAB-accredited certificates within the scope covered by the suspension. Once ANAB notifies it of the suspension, the CB must provide ANAB a list of clients with accredited certificates. ANAB staff determine the conditions for removing the suspension, communicate these to the suspended CB, and monitor the responses and corrective actions of the CB. Corrective actions must normally be submitted and accepted within six months. Failure to do so within the prescribed time frame may lead to withdrawal of the accreditation. Grounds for suspension or withdrawal may include:

- Failure by the CB to conform with accreditation requirements.
- Failure by the CB to maintain an effective audit management program in keeping with the current version of ISO/IEC 17021-1 and any related documents.
- Inability or unwillingness of the CB to ensure conformity of its certified organizations to applicable standards.
- A major NCR previously issued and not addressed effectively.
- Ineffective correction and/or corrective action taken, or corrective action not implemented within a specified time period.
- An NCR with or failure to execute the ANAB Accreditation Agreement.
- Improper use of the certificate of accreditation or the ANAB accreditation symbol.
- A complaint or a number of complaints indicating the management system of the CB is not being maintained.
- Failure to meet financial obligations to ANAB.
- Falsification of any nature.

Upon receiving notification of an accreditation withdrawal, the CB provides ANAB with a copy of the notification it plans to provide its certified and applicant clients informing them of the withdrawal, requiring the client to return any ANAB-accredited certificate, and advising them of the process for transferring to another ANAB-accredited CB. The CB must then send the ANAB-approved notice to its clients within 15 calendar days. ANAB keeps a record of suspensions and withdrawals on its website, including the effective dates of the suspension/withdrawal and an explanation of the basis for the suspension/withdrawal.

As noted above, accreditation suspension decisions are normally made by a panel of the ANAB Management Systems Accreditation Council. Under certain conditions, however, ANAB staff may also issue suspensions. ANAB Accreditation Rule 11 (see below) outlines the conditions and procedures for such situations.

4.1.2. ANAB Accreditation Rules

ANAB issues accreditation rules (ARs) that represent ANAB's position or policy with regards to certification program operational elements addressed in ISO/IEC 17021. Accreditation rules sometimes expand on or clarify requirements contained in ISO/IEC 17021. Conformance with ANAB accreditation rules is a requirement for ANAB accreditation.

Accreditation Rule 30, Accreditation Program for Occupational Health and Safety Management Systems. ANAB issued AR 30 in 2017 and updated it in 2018. AR 30 incorporates requirements from IAF MD 22 (International Accreditation Forum, 2018) concerning how to determine the scope of accreditation for ISO 45001:2018, and references and adopts the IAF Technical Clusters and Critical Codes found in Appendix D of IAD MD 22 (see above). AR 30 then describes how ANAB determines the witnessing requirements for a CB, which it bases on the CB's client base, technical clusters in which it can demonstrate competence, and critical codes that apply (ANAB, 2018d).

For any AB wishing to expand the scope of an initial ISO 45001:2018 accreditation, ANAB assigns the application to a competent reviewer who prepares an initial assessment. Before granting any scope extension in a new technical cluster, ANAB requires a witnessed audit regardless of whether the IAF code is critical. If a CB is already accredited for a critical IAF code in a technical cluster, ANAB can extend the scope of accreditation to any non-critical codes within that cluster without further witnessing. (See Appendix D of MD 22 for further details about technical clusters and critical codes.)

AR 30 also addresses the migration of any CB's accreditation from ANSI/ASSE Z10, BS OHSAS 18001, or CSA Z1000 to ISO 45001. IAF, ISO, and the OHSAS Project Group (publishers of the OHSAS 18001 standard) agreed to a migration period ending three years after publication of the ISO 45001 standard (i.e., March 31, 2021).[24] The first step requires CBs to apply for migration themselves (i.e., a change in their accreditation to ISO 45001) through an application process administered by ANAB through EQM. Once the CB is migrated, it must begin the process of migrating clients to ISO 45001:2018. To help monitor CB progress in migrating certificates, AR 30 requires CBs to provide ANAB with data on the number of ANAB-accredited certificates they have issued for each OHSMS standard every six months beginning January 2019, and every month starting June 30, 2020, through the end of the migration period.

Accreditation Rule 5, Compliance with Legislation and Regulatory Requirements. AR 5 begins by clarifying that management system standards such as ISO 14001 and ISO 45001 require compliance with applicable legislative and regulatory requirements, but the conformance audit performed by the CB is not a compliance audit (ANAB, 2018a). As a result, a certification audit must not certify or make any statement or declarations indicating whether the organization is or is not in legal compliance.[25] The CB must instead focus on the many elements of the standard that impact or address compliance. While not stated in AR 5, these include whether the organization:

- Demonstrates a commitment to fulfill legal requirements (ISO 45001:2018, 5.2, "OH&S Policy").
- Consults with workers on how to fulfill legal requirements (ISO 45001:2018, 5.4, "Consultation and participation of workers").
- Takes into account legal requirements when identifying the risks and opportunities that need to be addressed (ISO 45001:2018, 6.1, "Actions to address risks and opportunities").
- Determines and has access to up-to-date legal requirements applicable to its hazards, OHS risks, and OHS management system, and takes these into account when establishing, implementing,

[24] Extended by the IAF to September 11, 2021, due to COID-19.

[25] It is notable that AR5 limits the evaluation to the organization's capacity to monitor and maintain compliance with "legislation and regulatory requirements." ISO 45001:2018 addresses both legal and "other" requirements, with "other" requirements defined as "requirements … that an organization … chooses to comply with." Examples of such requirements could include parent company policies, collective bargaining agreements, voluntary industry codes of conduct, contractual conditions, etc.

maintaining, and continually improving its OHSMS (ISO 45001:2018, 6.1.3, "Determination of legal and other requirements").

- Plans and takes action to address legal requirements (ISO 45001:2018, 6.1.4, "Planning action").
- Takes into account its legal requirements when establishing communications processes (ISO 45001:2018, 7.4, "Communication").
- Has procedures in place to respond to changes in legal requirements (ISO 45001:2018, 8.1.3, "Management of change").
- Considers its legal requirements when establishing processes for monitoring, measuring, analyzing, and evaluating performance (ISO 45001:2018, 9.1, "Monitoring, measurement, analysis and performance evaluation").
- Has established, has implemented, and maintains processes for evaluating legal compliance; maintains knowledge and understanding of its compliance status; and retains documentation of its compliance evaluation results (ISO 45001:2018, 9.1.2, "Evaluation of compliance").
- Gives consideration during management reviews to any changes in legal requirements and reviews the results of compliance evaluations (ISO 45001:2018, 9.3, "Management review").
- Has a corrective and preventative action process in place that identifies noncompliance, takes action to control and correct it, determines the root cause, and takes action to prevent further recurrence, and monitors the effectiveness of actions taken (ISO 45001:2018, 10.2, "Incident, nonconformity and corrective action").

AR 5 specifies that in the event a CB assessment team observes evidence of noncompliance with a legal requirement during a conformance audit it may still issue a certificate, but only if it is "satisfied that the management system [process] addresses such noncompliances and when in the aggregate such noncompliances are not determined to indicate a major nonconformity."[26]

The final provision of AR 5 addresses situations where the organization being audited fails to make information related to legal or regulatory compliance available to the CB by making a claim of legal protection or asserting its proprietary nature. If this should occur, the CB shall not grant a certificate unless it can demonstrate through other evidence that the system conforms with all other requirements related to legal compliance.

Accreditation Rule 11, Suspension of Accreditation by ANAB Management Staff. AR 11 outlines situations where ANAB may not follow the suspension procedures contained in MA 5000 (ANAB, 2014c). Under AR 11, the Accreditation Council has authorized ANAB staff to issue suspensions without initiating a panel hearing when specific situations arise. These include:

- Past due payment of fees.
- Failure to complete required witnessed audits.
- Failure to submit a plan for a major nonconformity.

[26] This point merits further investigation. The passage suggests that a certified organization is only expected to be in compliance with legal requirements "in the aggregate," and that a system that conforms with ISO 45001 addresses non-compliance with legal requirements but does not ensure it. The common understanding of ISO 45001 is that compliance with legal requirements is a baseline condition.

Suspensions based on such grounds may be issued for a period of up to 180 days, and may be lifted upon satisfactory response from the AB (e.g., payment of past due fees, completion of witnessed audits, acceptance of a plan to address a nonconformity).

Accreditation Rule 8, Conforming with the Requirement for Initial Assessment of Auditor Performance During an On-site Audit. ANAB issued AR 8 to communicate the approaches it deems acceptable for CBs seeking to conform to the requirement (in ISO/IEC 17021) that CBs develop a process for conducting an initial assessment of the competence and performance of auditors during onsite audits (ANAB, 2018b). AR 8 indicates any of the following approaches will be deemed conforming:

- Assessment of the auditor by competent CB personnel during an onsite audit.
- Prior assessment of the auditor by competent personnel of another CB accredited by an IAF management systems MLA signatory, provided the CB can obtain records of the evaluation.
- An auditor holding a current and valid certification issued by an ISO/IEC 17024-accredited body[27] that has incorporated a competency-based onsite skill examination, provided the CB can obtain records of the onsite evaluation results.

These requirements apply to the initial assessment of auditor performance only. It does not apply to the requirement of ISO/IEC 17021-1 for ongoing assessments of auditor performance.

Accreditation Rule 9, Certified Organizations Business Continuity and Disaster Recovery. ANAB issued AR 9 to provide CBs with instructions on how to address situations where they may be unable to conduct scheduled assessments due to disruptions to their client's business. Such disruptions may be brought about by natural disasters, terrorism threats, information system attacks, geopolitical tensions, pandemic, and labor strikes, among other causes (ANAB, 2014a). The rule requires each CB to do the following:

- Establish a policy and procedures outlining the steps it will take in the event a client is affected by a business disruption.
- Develop a list of questions it will ask the client, such as:
    - When will the facility or organization be able to function?
    - Will the facility use alternate production or distribution sites, and are these covered under the current certification?
    - If the client is certified to a management system standard that requires a disaster recovery plan or emergency response plan, has the client implemented the plan and was it effective?
    - To what extent has operation of the management system been affected?
- Consider alternative assessment approaches, such as reviewing key documents offsite.
- Ensure that any deviation from normal assessment procedures and accreditation requirements is justified and communicated to ANAB.

[27] ISO/IEC 17024:2012 *(Conformity Assessment—General Requirements for Bodies Operating Certification of Persons)* applies to organizations that certify individuals against various certification schemes (International Organization for Standardization, 2018b). Examples of occupations covered by such schemes range from food inspector to auditor to cybersecurity specialist (International Organization for Standardization, 2016).

Accreditation Rule 10, CB Management of Marketing and Relationships with Bodies that Provide Management Systems Consulting. ISO/IEC 17021 prohibits CBs from marketing consultation services. ANAB issued AR 10 to provide clear indication of what it considers to be conformance or nonconformance with this provision. In AR 10, ANAB notes that the separation of consulting and certification has been a problem in the past, "as evidenced by the frequent complaints from CBs about other CBs, and complaints from other stakeholders" (ANAB, 2014b). ISO/IEC 17021 uses the examples of preparing manuals or procedures, or giving specific advice or solutions toward development of a management system, as activities it considers "consulting." AR 10 requires a CB to take a number of steps to avoid nonconformance with these provisions of ISO/IEC 17021. These include:

- Conducting a rigorous risk analysis to analyze and document relationships that could affect confidentiality, objectivity, and impartiality, and demonstrate how it manages these risks.
- Ensuring its website does not include any direct links to a body that provides management systems consulting.
- Avoiding any joint sales presentations to a potential or existing certified client with a management systems consultancy.

Accreditation Rule 17, Application of IAF MD 2 (Transfer of Accredited Certification). This accreditation rule clarifies the conditions under which certifications are eligible to be transferred from one CB to a different, ANAB-accredited CB (ANAB, 2017a). These include:

- Any certification may be transferred from one ANAB-accredited CB to a different ANAB-accredited CB.
- All certifications accredited by an IAF MLA management system signatory at level 3 (i.e., ISO/IEC 17021-1) are eligible for transfer, even if the certifying body is not a level 4 or 5 signatory (e.g., ISO 45001).
- Any CB accepting a transferred certificate must verify the certificate by contacting the issuing CB.
- Documentation associated with the certified organization must be provided to the CB accepting the certificate transfer. If this information is provided by the certified organization (and not the certifying CB), the accepting CB must verify the information with the certifying CB.
- The certifying organization shall not suspend or withdraw the certificate following notification that the organization is transferring to another, ANAB-accredited CB, as long as the organization continues to meet the requirements of certification.

Accreditation Rule 18, Scheduling of Witnessed Audits Required to Maintain ANAB Accreditation. This accreditation rule primarily addresses how ANAB administers its witnessed audit program (ANAB, 2017b). It details the identification of audits to be witnessed, the scheduling of those audits, ANAB notification requirements, what happens when there are changes to the schedule or the assessment team makeup, documentation to be completed by the CB, and ANAB fees.

Accreditation Rule 19, Remote Assessments. ANAB issued this accreditation rule to identify scenarios where it may use remote assessments to supplement, or substitute for, onsite assessment activities, and the conditions that must be satisfied to do so (ANAB, 2018c). The rule also identifies activities for which remote assessments are not appropriate. The list of activities ANAB may consider for remote assessment include:

- An office assessment, when an ANAB-accredited CB is seeking accreditation for a new program.
- Witnessing, when a CB is conducting a remote audit.
- An office assessment of another location of a CB.
- A complaint investigation.
- Verification of corrective action implementation.
- When timing of the assessment does not support the travel logistics required to conduct the assessment onsite.
- When ANAB has determined the activity has a low risk level.
- When an activity planned for the onsite assessment could not be completed and extending the onsite assessment is not the best resolution.
- When there are unavoidable changes in scheduling for the ANAB assessment team and/or the CB (e.g., illness, travel challenges or restrictions).
- When an onsite assessment is not required for the relevant standard or scheme.
- When ANAB is confident that the assessment objectives can be achieved via remote assessment activities.
- In special situations for which ANAB management grants approval.

To be eligible for remote assessment, the CB must be able to provide ANAB electronic access to relevant documents and to host virtual meetings. ANAB will also consider the CB's track record of conformance during prior assessments.

Accreditation Rule 42, IAF Requirement for Accredited Certification Bodies to Issue Accredited Management Systems Certifications. This rule clarifies that, consistent with IAF Resolution 2015-14, each ANAB-accredited CB may issue only accredited management system certifications that fall within the CB's scope of accreditation. A CB may issue certifications outside this scope, but they may not be identified or branded as an "accredited" certification and may not bear the "ANAB-accredited" logo (see PR1018 below and Figure 2).

4.1.3. ANAB Policies

PR 1018, Policy on Use of ANAB Accreditation Symbols and Claims of Accreditation. This policy outlines conditions for use of ANAB logos, symbols, and claims of accreditation (ANAB, 2018e). The policy first prohibits any use of the ANAB logo itself (on left in the figure below). ANAB has developed logos that may be used by CBs accredited by ANAB for specific types of standards. An ANAB-accredited management system CB may use the logo on the right, in the figure below. Any CB that maintains its ANAB accreditation may use the "ANAB-accredited" logo and the ANAB name in its advertising, marketing materials, certificates, and reports. If it loses its ANAB accreditation it must discontinue using these assets immediately.

ANAB-accredited certified organizations may also use the "ANAB-accredited" logo, but only alongside the logo of the ANAB-accredited CB that issued the certificate; the ANAB logo also must not exceed the size of the CB logo. Use of the ANAB-accredited logo may not be transferred from one organization to another regardless of the relationship between the two organizations. Use of the logo must discontinue immediately upon withdrawal of the certificate or the certificate-granting organization's ANAB accreditation.

Figure 2. Authorized use of ANAB and ANAB-Accredited logos (Source: ANAB PR 1018).

4.1.4. ANAB HeadsUp

Periodically, ANAB issues "HeadsUp" communiques to inform the CB community about current or upcoming issues, clarify ANAB policies or procedures, discuss trends from audits, or convey developments at ANAB or IAF. Recent communications of note for this project are summarized below.

HU 393, ISO 45001 Migration Process for OHSMS CBs and CB Clients. This HeadsUp was issued in February 2018 in anticipation of the release of ISO 45001. It references the IAF migration process and timeline for migration of OHSAS 18001–certified clients to ISO 45001. ANAB first indicates that, in addition to OHSAS 18001, it intends to migrate any ANSI/AIHA Z10 or CSA Z1000 accreditations to ISO 45001. It then encourages CBs to apply early for migration, announces the migration process fee ($1,250), and indicates the evaluation will involve one day of document review. Supporting documentation to be provided includes each CB's migration plan for existing and new certification clients, competence of personnel, migration audit duration, and evidence of conformance with ISO/IEC 17021-10 and IAF MD 22 (see above).

HU 399, ISO 45001:2018 Unaccredited Certificates. ANAB issued this HeadsUp in March 2018 to address a gap in instructions on how a CB should migrate an unaccredited ISO 45001 certificate to accredited status. A CB might have issued such a certificate before becoming accredited for ISO 45001; the communique clarifies that, once the CB has been thus accredited, ANAB AR 42 (see above) provides for re-issuance of such certificates, which will bear the "ANAB-accredited" logo (see PR 1018 above).

5. ISO/IEC 17021

ISO/IEC 17021 *(Conformity Assessment—Requirements for Bodies Providing Audit and Certification of Management Systems)* specifies the requirements for CBs performing management system audits. Part 1 contains the general requirements covering certification against all management system standards, while additional parts cover requirements that are specific to individual standards. Part 10 covers certification of OHSMS.

5.1. Part 1: Requirements

First issued in 2015, ISO/IEC 17021 Part 1 sets forth the requirements for CBs performing management system audits, including environmental, quality, and information security management systems.

Part 1 (Section 4) begins by setting out the **general principles** of management system certification, namely that certification shall be undertaken in a manner that inspires confidence among various stakeholders (including the organizations being certified, customers of those organizations, governments, non-governmental organizations, and members of the public). A CB inspires confidence by following the remaining general principles: impartiality, competence, responsibility, openness, confidentiality, responsiveness to complaints, and the use of a risk-based approach.

Section 5 of ISO/IEC 17021 next describes the **general requirements**—for instance, CBs must be legal entities and have a legally enforceable agreement with each organization they are auditing. The bulk of the remainder of the general requirements section centers on steps the CB must take to maintain its impartiality. This includes a commitment to impartiality from the CB's top management, as well as having a process to assess and mitigate potential conflicts of interest. Threats to impartiality might include CBs certifying each other's management systems, being in any way linked to a management system consultancy that offers consulting on the type of system the CB audits, or having any financial pressures that might induce them to compromise their integrity.

Section 6 goes on to outline **structural requirements,** i.e., requirements for the CB's own organizational structure. The CB shall document its organizational structure and identify the top management responsible for ensuring impartiality, developing certification activities, performing audits, and leading other administrative and operational functions. A CB with multiple offices, partnerships, franchises, or similar relationships shall also have a process for controlling them, as well as taking into account the way that relationship or the activities of those entities might affect the CB's impartiality or competence.

Section 7 on **resource requirements** largely deals with a CB's personnel. Personnel shall be competent in the particular type of management system they will use (environmental, quality, or information security) and the geographic area where the CB conducts audits. The CB must have a way to assess and monitor that competence (as discussed in Annex B). Many relevant methods would be used in the hiring process in other industries as well such as a review of resumes, references from previous employers, and interviews. Other methods can be used to assess competence on an ongoing basis, such as post-audit debriefs, observing personnel in their work, or examinations.

For personnel involved in audits, the CB shall have enough auditors with the expertise to support the audits the CB performs, ensure that they are knowledgeable about the audit process and certification requirements, provide them training, and have a documented process for monitoring auditor performance.

If a CB subcontracts any certification activity or uses any external auditors or technical experts, the CB's process for ensuring their competence and impartiality must be similar to the one it uses with its own staff.

The next section of ISO/IEC 17021 (Section 8) deals with **information requirements:**

- In terms of information made publicly available, the CB shall publish (e.g., on a website) information about the audit process, the types of management systems it audits, the certification process, use of its name and logo, the process for handling requests for information or complaints, and a policy on impartiality. Other information it must provide to the public on demand includes the status, scope, and geographical location covered by a given organization's certification, and a list of the geographic areas in which the CB operates.

- In terms of information exchanged between the CB and its client organizations, the CB must provide the client organization with information about certification and the audit process, information about fees, a description of the responsibilities of the client organization, and information on the process for handling complaints and appeals. The client organization itself must inform the CB of changes to the company's legal status or ownership, management, contact information, scope of operations under its management system certification, and major changes to the system itself.

When a CB provides a certification document to a client organization, the document shall include the name and geographic location of the client and any of its sites covered by the certification, the effective start and expiration date of the certification, a unique identification code, and the scope of the certification.

Each CB must also have rules governing the way client organizations make statements about their certification or display any certification marks, to make it clear what type of management system has been certified, which CB granted the certification, and what such certification means or represents. Should any client organization misrepresent its certification or misuse marks, the CB shall have a legally enforceable arrangement to request corrective action.

The final information requirement centers on confidentiality. The CB must have legally enforceable mechanisms in place to ensure that information about client organization obtained during the certification process remains confidential.

Section 9 is the most substantial section of ISO/IEC 17021 and deals with **process requirements**, i.e., the process of auditing and certification, and covers:

- Pre-certification activities.
- Planning audits.
- Initial certification.
- Conducting audits.
- Certification decision.
- Maintaining certification.
- Appeals.
- Complaints.
- Client records.

Pre-certification activities begin with the client organization submitting an application to the CB, review of that application by the CB, the development of an audit program for the client (including a two-stage initial audit, surveillance audits in the first and second years, and a recertification audit in the third year), determination of the time needed for the audit, and development of a plan for multi-site sampling (if the client organization has multiple sites and the certification scheme allows sampling).

Planning audits entails the CB determining the objectives, scope, and criteria being used for the audit; choosing audit staff, any observers, technical experts, and client organization guides; developing an audit plan; and communicating with the client organization on these items.

An **initial certification audit** of a management system is carried out in two stages. The first preparatory stage includes a review of the client's management system documentation, review of the client's understanding of the standard being audited, gathering of information on the scope of the client's management system (e.g., information about the site, processes and equipment, or applicable regulatory requirements), and an evaluation of whether the client organization conducts its own audits and management reviews. The second stage is an onsite audit evaluating the client's implementation of

the management system, in which the CB gathers information on how the management system conforms with the applicable standards and regulatory requirements.

The **conducting audits** section of ISO/IEC 17021 details the actual audit process, including holding an open meeting, the need for communication among the audit team and between the CB and client organization during the audit, ways to obtain and verify information (such as interviews, observation, and document review), recording the audit findings, coming to an audit conclusion, holding a closing meeting, and preparing an audit report. If any nonconformities were found during the audit, the client is to identify the cause and perform corrective actions, with the CB reviewing these.

Post-audit, the audit team provides its findings to the CB to make the **certification decision** based on the audit report, confirmation that any nonconformities were corrected, and the audit team's recommendation about certification.

To **maintain certification**, the CB is required to conduct surveillance audits, which may be onsite but typically are not as extensive as a full audit. At the time of recertification, the CB will conduct an onsite recertification audit that evaluates the continued effectiveness of the client's management system in light of any changes. At times it may also be necessary to conduct special audits, such as when the client wishes to expand the scope of its certification, or to make an unannounced audit in response to complaints. In cases where certification cannot be maintained, the CB can suspend the certification with the possibility for the suspension to be ended if the issues are addressed.

The last sections on process requirements specify that the CB is to have a documented process for handling **appeals** and **complaints,** as well as maintaining records on the CB's clients and audits.

The final section of ISO/IEC 17021 Part 1 (Section 10) deals with **management system requirements for CBs** themselves, which can either be of a general nature or follow the requirements of ISO 9001. For the former, the CBs shall conduct internal audits of its own management system at least once a year, taking corrective actions if any nonconformities are identified.

Part 1 also includes several normative and informative **appendices:**

- Annex A presents required knowledge and skills for CB staff performing various functions.
- Annex B presents examples of methods for evaluating personnel's competence.
- Annex C is a flow chart illustrating an approach to determining competence of personnel.
- Annex D lists desired behavioral characteristics for CB staff involved in certification activities (e.g., ethical, open-minded, diplomatic).
- Annex E is a flow chart illustrating a typical audit and certification process.

5.2. Part 10: Competence Requirements for Auditing and Certification of Occupational Health and Safety Management Systems

Issued in 2018, ISO/IEC 17021 Part 10 specifies competence requirements (beyond what Part 1 already requires) for organizations conducting audits and certification of OHSMS (International Organization for Standardization, 2018a). Competence requirements are defined for:

- Auditors.
- Personnel reviewing audit reports and making certification decisions.
- Other personnel.

5.2.1. Competence of Auditors

This section of ISO/IEC 17021 Part 10 is structured around the main sections of the ISO 45001 standard, and identifies competencies that auditors (or the collective audit team) will need to properly assess the OHSMS. This begins with knowledge of **key terminology, principles, and processes** of the OHSMS, such as hazards and OHS risks, hierarchy of control, procurement, and shared control over work (e.g., onsite contractors and temporary agency employees). They shall also have knowledge of the **context of the organization** being audited, including potential issues the organization may face and potential interested parties. In the area of **leadership and worker participation,** auditors shall have knowledge of the impact of leadership on safety culture, as well as methods for consulting with workers and getting their participation, including knowledge of barriers and obstacles. The audit team shall understand the **legal framework** under which different organizations must operate (i.e., which laws, regulations and "other" requirements apply), including legal requirements related to worker involvement, protection of personal health information, and the establishment of health and safety committees.

Audit teams need to understand **OHS risks and methods used to identify and assess them,** such as risk assessment, job hazard analysis, and failure mode and effects analysis. Knowledge shall cover risks associated with internal or external sources, potential emergency situations, subcontracting and multiemployer workplaces, planned or unintended changes, work organization, and human/social factors. They shall also have knowledge of **opportunities** that can be leveraged, such as adapting work to workers, changing the work organization, and workplace or workstation layout. Knowledge of potential **emergency situations** that could arise for a given organization will help auditors determine how well such organizations have assessed these and planned to address them.

OHSMS auditors need knowledge of **OHS performance measures**, including both lagging and leading indicators, and how to determine whether an organization is meeting OHS goals. They also need good understanding of **approaches for controlling or eliminating OHS risks** and how to apply the hierarchy of controls. Knowledge of **incident investigation** techniques will help OHS auditors evaluate how effectively an organization conducts investigations, including its use of root cause analysis.

5.2.2. Competence of Personnel Reviewing Audit Reports and Making Certification Decisions

The competency requirements for persons reviewing audit reports and making certification decisions are very similar to those described above for auditors.

5.2.3. Other Certification Personnel

For other certification personnel, Part 10 highlights competence related to OHS terminology, principles, and concepts, as well as the context of the organization.

6. SUMMARY AND CONCLUSIONS

Management system standards serve many purposes. One of the primary purposes is to signal to internal and external stakeholders that a specific aspect of an organization's operations (quality, environment, occupational health and safety) is managed in an effective and controlled manner. Conformance to an established standard, and verification of that conformance by an external examiner, is a way to communicate the organization's commitment and achievement in that specific area.

An "ecosystem" of certifiers and accreditors has emerged to facilitate the acceptance and recognition of management system conformance globally. For this system to be robust and deliver on its promise, the certifiers and accreditors need to be competent, independent, and free of conflicts of interest. This report finds that the integrity of this system relies on multiple layers of quality control checks and balances that have been put in place over time. When operating properly, the system should be capable of identifying those organizations who are both committed to improving workplace health and safety and equipped with the resources and capabilities to do so, and thus worthy of certification. Further, to maintain certification such organizations must demonstrate not only ongoing conformance to the standard, but continuous improvement in the performance of their system. It is worth noting that the "certificate" of conformance to an OHSMS standard belongs not to the organization but to the certifier, and it can be suspended or withdrawn at any time. This is communicated by the CB to each organization seeking certification, and the conditions for suspending or withdrawing certificates are included in their contracts for certification services.

Certification bodies accredited through this system will have a deep understanding of effective occupational safety and health management (as spelled out in the standards), and personnel who are capable of assessing an organization's ability to manage its operations in accordance with the practices described by the standards. Their audit team members must be trained to seek and evaluate objective evidence of conformance to each element of the standard, and to make an assessment of conformance that is clear, concise, and traceable back to the evidence they have collected. Final certification decisions are made only after the audit case file, including the audit team report, is examined by a review team that is independent of the audit. The ISO/IEC 17021 standard serves as the guide for CBs as they establish, operate, maintain, and improve their management system certification practice. ISO/IEC 17021-10, issued in 2018, is a separate standard specifically focused on auditing OHSMSs.

To issue certificates that will be recognized and accepted globally, certification bodies seek accreditation from an accreditation body that is a member of the International Accreditation Forum and that has signed the IAF Multilateral Recognition Arrangement (MLA). As an IAF member and MLA signatory, an AB must adhere to certain IAF procedures and implement a set of mandatory processes and controls. ISO/IEC 17011 serves as the guide for implementing best practices in the area of management system accreditation.

Under this system, the accreditation process involves a detailed review of the CB and its conformance to ISO/IEC 17021. The review considers how the CB is organized (including whether it is independent of any management system consulting entities), how it ensures the competence of its auditors, how it plans and conducts its audits, how it makes certification decisions, and how it addresses complaints, among other things. Accreditation also involves onsite assessments of the CB's office operations as well as formal observations in the field, made during "witnessed" audits. Accreditation is granted for defined scopes of activity, and any extension of scope is subject to additional review and assessment.

Accreditation bodies, in turn, are subject to review prior to their acceptance as IAF members and IAF MLA signatories. These assessments follow IAF guidelines and procedures, but are generally conducted by IAF-recognized regional accreditation groups such as the InterAmerican Accreditation Cooperation. IAF assessments also involve onsite visits and operational reviews by a competent assessment team.

This analysis demonstrates that organizations that are certified to OHSMS standards such as ISO 45001 have undergone a thorough review of their organization's implementation of the requirements of that standard. The rigorous accreditation process described above ensures that Certification Bodies and the organizations they certify demonstrate competence and are knowledgeable in the industries they serve and operate in. The rigor of the review by an accredited Certification Body yields confidence among interested stakeholders that the certified organization has achieved a high degree of performance in the management of occupational health and safety.

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