

Pointed in the **RIGHT** **DIRECTION**

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In 50 Words Or Less

- The latest edition of ISO 19011 includes important changes to the auditing standard, most notably its expansion in scope to cover all management systems.
- While this and other updates broaden the usability of the standard, additional guidance on internal and supply chain audits is still needed.

LAST NOVEMBER, the International Organization for Standardization (ISO) published a new edition of *ISO 19011—Guidelines for auditing management systems*.¹ This latest edition of the standard marks a further evolution in management system auditing and in ISO's approach to the drafting of management system standards.

First, as part of the evolution in ISO's approach to standard development, the scope of ISO 19011 has expanded. Whereas the scope of the standard's 2002 edition was limited to quality and environmental management system audits, the guidelines in the 2011 edition are intended to cover all management system disciplines. As such, the development of ISO 19011 is the harbinger for the efforts now under way to standardize all of the ISO management system standards with a common high-level structure.²

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Second, as part of an evolution in management system auditing, ISO 19011 introduces new concepts and expands on topics not fully addressed in the 2002 edition. This includes guidance on identifying and evaluating risks in audits, and expanded guidance on planning and conducting audits through the selection of appropriate audit methods and the use of various audit sampling techniques.

While this edition of ISO 19011 broadens its usability, it is still not perfect. There are inconsistencies in the terminology used among the various sections of the standard, and some important concepts are only superficially addressed within the standard. The most significant deficiencies relate to the lack of guidance for performing second-party audits, such as supply chain audits, and to the lack of sufficient guidance related to risk-based auditing.

To understand the future auditing challenges related to ISO 19011:2011, it's necessary to examine the past development and present content of the standard.

ISO 19011: past development

Management system auditing standards are not new. Their development has paralleled the development of ISO's management system specification standards.

In 1987, ISO published ISO 9001. This action resulted in the development of three ISO quality management system (QMS) auditing standards by 1991.

In 1996, ISO Technical Committee (TC) 207 completed its work on ISO 14001:1996, which set out environmental management system requirements (EMS), along with a set of three companion auditing standards that were based largely on the ISO 10011 standards (see Table 1).

Consolidation of quality and environmental auditing guidelines (the drafting of ISO 19011:2002): In 1998, the ISO Technical Management Board directed TC 176 and ISO TC 207 to participate in a joint working group to develop a combined auditing standard. The goal was to provide greater consistency and compatibility between QMS and EMS auditing.

ISO 19011:2002—Guidelines on quality and/or environmental/management systems auditing,³ was published in October 2001. The standard was intended to address the full range of auditing activities, including internal (first-party), supply chain (second-party) and external (third-party) audits. Table 2 lists the principal clauses of ISO 19011:2002. This standard replaced all of the separate quality and environmental audit standards.

The 2002 edition of ISO 19011 was subsequently used in drafting *ISO/IEC 17021:2011—Conformity assessment—Requirements for bodies providing audit and certification of management systems*.⁴ Unlike the nonmandatory guidance in ISO 19011, ISO 17021 defines requirements used for accreditation of management system certification bodies (registrars) and establishes the requirements for external third-party audits for certification purposes.

Development of the U.S. supplement to ISO 19011 (ANSI QE 19011S-2004): During the development of ISO 19011, U.S. experts expressed concerns that, because of the focus on third-party certification audits, the guidance was inadequate for other types of management system audits. *ANSI/ISO/ASQ QE 19011S-2004—Guidelines on quality and/or environmental management systems auditing—U.S. version with supplemental guidance added*,⁵ was developed to fill this gap. This standard provided

additional guidance pertaining to internal audits, supplier audits and the use of the standard by small to medium-sized organizations. To simplify its use, QE 19011S:2004 also contained the complete text of ISO 19011:2002.

Revision of U.S. supplement to ISO 19011 (ANSI QE 19011S-2008): The nature of management system auditing continued to evolve as other new management system standards were drafted and published. It became increasingly apparent that ISO 19011:2002 was inadequate because it focused only on quality and environmental management system audits.

Initial quality and environmental audit guidelines / TABLE 1

ISO 10011-1:1990	<i>Guidelines for auditing quality systems—Part 1: Auditing</i>
ISO 10011-2:1991	<i>Guidelines for auditing quality systems—Part 2: Qualification Criteria for Quality Systems Auditors</i>
ISO 10011-3:1991	<i>Guidelines for Auditing Quality Systems—Part 3: Management of Auditing Programs</i>
ISO 14010:1996	<i>Guidelines for environmental auditing—General principles</i>
ISO 14011:1996	<i>Guidelines for environmental auditing—Audit procedures—Auditing of environmental management systems</i>
ISO 14012:1996	<i>Guidelines for environmental auditing—Qualification criteria for environmental auditors</i>

The ANSI Z1 Accredited Standards Committee subsequently revised the 2004 standard to apply generally to all management system audits. In particular, new guidance was added to clause 7 to provide competence criteria and evaluation methods for audits of occupational health and safety management systems. The result was *ANSI/ISO/ASQ QE 19011S-2008—Guidelines for management systems auditing—U.S. version with supplemental guidance added*.⁶

Revision of ISO 19011:2002 (publication of ISO 19011:2011): In 2007, ISO conducted a systematic review of ISO 19011:2002. This review determined that the standard needed to be made more generic and expanded to apply to all management system disciplines. It was believed a revision would provide benefits to the many organizations that have implemented management systems covering different disciplines. There also was an expressed desire to address new developments in management system auditing, such as risk-based, process and remote auditing.

The revision of ISO 19011:2002 was accomplished through an expedited series of meetings of a multidisciplinary working group. ISO published the revised standard in November 2011.

ISO 19011: present content

Although there was reorganization and rearrangement of content within and between clauses 5 and 6, as well as the addition of new annexes, the overall structure of ISO 19011 has remained essentially the same (as shown in Table 3).

Clause 1—scope: ISO 19011:2011 is intended to be an umbrella standard that applies to all types of audits—both internal and external—as well as audits of all kinds of management systems.

It is specifically intended to provide guidance for audits of multiple management systems in a single audit program. This is sometimes referred to as audits of integrated management systems or integrated audit programs, although ISO 19011 defines this as a “combined audit.”

Like its previous edition, ISO 19011:2011 is not a specification, but it could be required under certain situations, such as contractual agreements.

Clause 3—terms and definitions: The definitions in ISO 19011:2011 are much the same as they were in the 2002 standard. There are a couple of notable differences:

Principal clauses in ISO 19011:2002 / TABLE 2

Clause	Subject of clause
1	Scope
2	Normative references
3	Terms and definitions
4	Principles of auditing
5	Managing an audit program
6	Audits activities
7	Competence and evaluation of auditors

Structure of ISO 19011:2011 revision / TABLE 3

Clause	Subject of clause
1	Scope
2	Normative references
3	Terms and definitions
4	Principles of auditing
5	Managing an audit program
6	Performing an audit
7	Competence and evaluation of auditors
Annex A	Guidance and illustrative examples of discipline-specific knowledge and skills of auditors
Annex B	Additional guidance for auditors for planning and conducting audits

1. In the 2002 edition, the term “competence” was defined as “demonstrated personal attributes and demonstrated ability to apply knowledge and skills.” In the 2011 edition, the new standardized definition of competence for ISO management system standards is used. This definition of competence is the “ability to apply knowledge and skills to achieve intended results.”

2. A definition of risk was added. The definition, “effect of uncertainty on objectives,” was adapted from ISO Guide 73:2009.⁷ This is also a standardized definition for use in all ISO management system standards.

Clause 4—principles of auditing: ISO 19011:2011 sets out general principles for management systems auditing in clause 4. These auditing principles are largely carried over from the 2002 edition and include:

- Integrity (previously called “ethical conduct”).
- Fair presentation.
- Due professional care.
- Independence.

- Use of an evidence-based approach.

One new principle has been added: confidentiality, which is defined as ensuring the security of information. In particular, auditors should exercise discretion in the use and protection of information obtained during an audit. The addition of this principle was driven by the increasing importance of data security issues associated with audits of information stored electronically.

Clause 5—managing an audit program: Clause 5 provides guidance for those who need to establish, implement, evaluate and maintain an audit program for an organization. The key management actions include:

- Establishing objectives for the audit program.
- Establishing the audit program, including extent, responsibilities, resources and procedures.
- Ensuring the implementation of the audit program.
- Monitoring and reviewing the implementation of the audit program.

An important addition and improvement to this clause is expanded guidance on the roles, responsibilities and competence needed by those who have responsibility for managing the audit program (in clauses 5.31 and 5.3.2).

Clause 6—performing an audit: Few changes were made to clause 6 in the 2011 revision. This clause continues to describe the general steps for planning and conducting individual audits.

Clause 7—competence and evaluation of auditors: Clause 7 was substantially rewritten to apply more generally to auditors of any management system discipline. The most significant difference from the previous edition was recognition that auditor competence should reflect the needs of the audit program.

It is not necessary for each auditor on the audit team to have the same competence or competence in

every area included in the audit. The important thing is that the overall competence of the audit team must be sufficient to achieve the audit objectives.

Table 4 lists the four-step process for evaluating and selecting auditors that is set out in clause 7.

Clause 7 continues to provide guidance on the criteria that should be considered in determining auditor competence. This includes personal behaviors, generic knowledge and skills needed by all auditors, as well as discipline and sector-specific knowledge and skills. Guidance is provided regarding the types of knowledge and skills needed to fulfill this requirement for any management system discipline. Guidance also is included to use in evaluating whether audit team leaders have the knowledge skills needed to manage and provide leadership to the audit team.

Illustrative examples of the discipline-specific knowledge and skills of auditors for various management system disciplines has been moved to Annex A. Table 5 lists the management systems disciplines included in Annex A of the 2011 edition.

ISO 19011 includes an expansive list of personal behaviors to be considered. These are based on qualities believed to be important for enabling auditors to act in accordance with the principles of auditing.

For the purposes of combined audits, ISO 19011 makes it clear that auditors who conduct audits covering multiple disciplines should have the competence necessary to audit the specific areas they are assigned, as well as have an understanding of the interactions and synergies between the different management systems.

ISO 19011: future impacts

There are several changes between the 2002 and 2011 editions that are likely to have future impacts both in how the standard is used and on management system auditing in general.

Increased use of combined audits: The most significant change in ISO 19011 is the expansion in scope to encompass all management systems that facilitates its use for combined audits.

The development and use of integrated management systems will continue to increase. The use of combined audits also is expected to grow as organizations seek to reduce costs by combining audits against several management system standards within a single audit program. Many of the changes in ISO 19011:2011 were made to address this need.

Management systems disciplines with competencies in Annex A of ISO 19011:2011 / TABLE 5

1	Quality management
2	Environmental management
3	Occupational health and safety
4	Resilience, security, preparedness and continuity management
5	Information systems security
6	Transportation safety
7	Records management

Shift of focus of ISO 19011 away from certification audits: ISO 19011 provided an important contribution to the development of ISO/IEC 17021 by setting out the basic principles and concepts underlying all management system audits.

In ISO/IEC 17021, the general guidance in ISO 19011 is focused and narrowed to define the requirements for third-party certification audits. This use of ISO 19011 as the foundation for developing sector-specific or application-specific audit specification standards is likely to continue.

Agreement on the definition of an audit: One thing that has remained consistent between the first and second editions of the standard is the definition of an audit. More importantly, it also is the same as the definition included in the newly proposed mandatory high-level structure for all ISO management system specification standards.

This means there is now a common understanding of and criteria for how an audit is defined across all management system disciplines.

Recognition of new audit methods and constraints: Today, auditors use a variety of audit methods: both on and off site (remote). Annex B includes a table listing various examples of the audit methods that can be used.

It is likely there will be increased reliance on remote auditing methods in the future. As auditing processes evolve, development of additional audit guidelines will be needed to ensure the validity and usability of the audit evidence being gathered.

Information management tools and techniques are changing rapidly: Such changes will affect how audit programs are managed and how audits are conducted. Increasingly, there will be less emphasis on physical documents, such as plans, records and reports. There will be more emphasis on ensuring the integrity and security of information stored in electronic databases or as unstructured data associated with remote surveillance devices. These emerging technologies are likely to foster the need for additional audit guidelines.

Evolution in determining the competence of audit personnel: Auditor competence is critical for obtaining and maintaining confidence in the audit process on the part of external parties.

Auditor competence was a major emphasis of the quality and environmental auditing standards that

Evaluation and selection process for auditors / TABLE 4

Step	Activity
1	Determine the competence needed to fulfill the needs of the audit program.
2	Establish evaluation criteria.
3	Select appropriate evaluation methods.
4	Conduct the evaluation.

were the precursors to ISO 19011:2011. The level of detail set out in the prior standards was too prescriptive to apply to the range of different audit situations now covered by ISO 19011. Now, everything from global supply chain audits in the context of sustainability reporting to internal audits conducted to evaluate the effectiveness of integrated management systems in a single manufacturing facility are covered by the standard.

Rather than setting out specific competence criteria as in the 2002 edition, ISO 19011:2011 takes a different approach. It describes the steps an organization should implement to establish the process and competence criteria for evaluating auditor competence for a particular audit program.

This change in approach will add flexibility to audit programs and enable organizations to define the appropriate audit program objectives and auditor competence criteria based on their individual audit program needs and requirements, not on a general one-size-fits-all approach as was used in ISO 19011:2002.

ISO 19011: supplemental guidelines

ISO 19011:2011 represents the next step in the evolution of ISO standard development—to develop a standard that applies equally and uniformly across all management system disciplines. This revision did not, however, fully address several of the topics that were initially identified as revision goals. These include risk-based auditing, as well as process and remote auditing techniques.

GET INVOLVED

If you want to become involved in these ongoing activities related to ISO 19011 and future standards development, contact ASQ's Standards Group at 800-248-1946 or standards@asq.org.

As a result of the focus shift away from third-party certification audits, much of the guidance in ISO 19011:2011 is now primarily focused on internal audits. This has resulted in guidance that may not be particularly useful for other external audit situations—such as supply chain audits. This is a topic that was covered in the U.S. supplements in 2004 and 2008. The ANSI Z-1 Management Systems Auditing Subcommittee has initiated action to develop supplemental guidance to address this weakness in the revision.

Audit standards for planning, conducting and evaluating management system audits must continue to evolve to address the challenges posed by technological changes, the expansion of management system standards, as well as the needs and desires of both user organizations and their stakeholders. **QP**

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