AMERICAN NATIONAL STANDARD

Guidelines for auditing management systems

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ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 19011 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.

This second edition cancels and replaces the first edition (ISO 19011:2002), which has been technically revised.

The main differences compared with the first edition are as follows:

— the scope has been broadened from the auditing of quality and environmental management systems to the auditing of any management systems;

— the relationship between ISO 19011 and ISO/IEC 17021 has been clarified;

— remote audit methods and the concept of risk have been introduced;

— confidentiality has been added as a new principle of auditing;

— Clauses 5, 6 and 7 have been reorganized;

— additional information has been included in a new Annex B, resulting in the removal of help boxes;

— the competence determination and evaluation process has been strengthened;

— illustrative examples of discipline-specific knowledge and skills have been included in a new Annex A;

— additional guidelines are available at the following website: www.iso.org/19011auditing.

Recommendation on the Use of ISO 19011:2011

The ASC Z1-Auditing Subcommittee recommends that users of this standard consider two points regarding additional guidance on management system auditing:

1. Concerning the ISO website, referenced in the Foreword above, the primary mission of ISO is the development of international standards through the use of formal consensus processes. Since website content may not be subject to the same consensus process as this standard, users should consider anything posted on this ISO website strictly as "more information" – as stated in the final draft international standard (FDIS) and agreed upon by vote, rather than "additional guidance."

2. Regarding the U.S. supplemental guidance on management system auditing that was previously published as ANSI/ISO/ASQ QE 19011S-2008: ISO 19011:2011 does not include information from the 2008 American National Standard concerning the use of ISO 19011 for internal audits, supplier audits and management system audits in small organizations. Since much of this information is still relevant and important, the ASC Z1 – Auditing Subcommittee has initiated work to transfer this information to new consensus documents as soon as feasible.

Introduction

Since the first edition of this International Standard was published in 2002, a number of new management system standards have been published. As a result, there is now a need to consider a broader scope of management system auditing, as well as providing guidance that is more generic.

In 2006, the ISO committee for conformity assessment (CASCO) developed ISO/IEC 17021, which sets out requirements for third party certification of management systems and which was based in part on the guidelines contained in the first edition of this International Standard.

The second edition of ISO/IEC 17021, published in 2011, was extended to transform the guidance offered in this International Standard into requirements for management system certification audits. It is in this context that this second edition of this International Standard provides guidance for all users, including small and medium-sized organizations, and concentrates on what are commonly termed "internal audits" (first party) and "audits conducted by customers on their suppliers" (second party). While those involved in management system certification audits follow the requirements of ISO/IEC 17021:2011, they might also find the guidance in this International Standard useful.

The relationship between this second edition of this International Standard and ISO/IEC 17021:2011 is shown in Table 1.

Table 1 — Scope of this International Standard and its relationship with ISO/IEC 17021:2011

Internal auditing	External auditing	
	Supplier auditing	Third party auditing
Sometimes called first party audit	Sometimes called second party audit	For legal, regulatory and similar purposes For certification (see also the requirements in ISO/IEC 17021:2011)

This International Standard does not state requirements, but provides guidance on the management of an audit programme, on the planning and conducting of an audit of the management system, as well as on the competence and evaluation of an auditor and an audit team.

Organizations can operate more than one formal management system. To simplify the readability of this International Standard, the singular form of "management system" is preferred, but the reader can adapt the implementation of the guidance to their own particular situation. This also applies to the use of "person" and "persons", "auditor" and "auditors".

This International Standard is intended to apply to a broad range of potential users, including auditors, organizations implementing management systems, and organizations needing to conduct audits of management systems for contractual or regulatory reasons. Users of this International Standard can, however, apply this guidance in developing their own audit-related requirements.

The guidance in this International Standard can also be used for the purpose of self-declaration, and can be useful to organizations involved in auditor training or personnel certification.

The guidance in this International Standard is intended to be flexible. As indicated at various points in the text, the use of this guidance can differ depending on the size and level of maturity of an organization's management system and on the nature and complexity of the organization to be audited, as well as on the objectives and scope of the audits to be conducted.

This International Standard introduces the concept of risk to management systems auditing. The approach adopted relates both to the risk of the audit process not achieving its objectives and to the potential of the audit to interfere with the auditee's activities and processes. It does not provide specific guidance on the organization's

risk management process, but recognizes that organizations can focus audit effort on matters of significance to the management system.

This International Standard adopts the approach that when two or more management systems of different disciplines are audited together, this is termed a "combined audit". Where these systems are integrated into a single management system, the principles and processes of auditing are the same as for a combined audit.

Clause 3 sets out the key terms and definitions used in this International Standard. All efforts have been taken to ensure that these definitions do not conflict with definitions used in other standards.

Clause 4 describes the principles on which auditing is based. These principles help the user to understand the essential nature of auditing and they are important in understanding the guidance set out in Clauses 5 to 7.

Clause 5 provides guidance on establishing and managing an audit programme, establishing the audit programme objectives, and coordinating auditing activities.

Clause 6 provides guidance on planning and conducting an audit of a management system.

Clause 7 provides guidance relating to the competence and evaluation of management system auditors and audit teams.

Annex A illustrates the application of the guidance in Clause 7 to different disciplines.

Annex B provides additional guidance for auditors on planning and conducting audits.

Guidelines for auditing management systems

1   Scope

This International Standard provides guidance on auditing management systems, including the principles of auditing, managing an audit programme and conducting management system audits, as well as guidance on the evaluation of competence of individuals involved in the audit process, including the person managing the audit programme, auditors and audit teams.

It is applicable to all organizations that need to conduct internal or external audits of management systems or manage an audit programme.

The application of this International Standard to other types of audits is possible, provided that special consideration is given to the specific competence needed.

2   Normative references

No normative references are cited. This clause is included in order to retain clause numbering identical with other ISO management system standards.

3   Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
audit
systematic, independent and documented process for obtaining **audit evidence** (3.3) and evaluating it objectively to determine the extent to which the **audit criteria** (3.2) are fulfilled

NOTE 1   Internal audits, sometimes called first party audits, are conducted by the organization itself, or on its behalf, for management review and other internal purposes (e.g. to confirm the effectiveness of the management system or to obtain information for the improvement of the management system). Internal audits can form the basis for an organization's self-declaration of conformity. In many cases, particularly in small organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited or freedom from bias and conflict of interest.

NOTE 2   External audits include second and third party audits. Second party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. Third party audits are conducted by independent auditing organizations, such as regulators or those providing certification.

NOTE 3   When two or more management systems of different disciplines (e.g. quality, environmental, occupational health and safety) are audited together, this is termed a combined audit.

NOTE 4   When two or more auditing organizations cooperate to audit a single **auditee** (3.7), this is termed a joint audit.

NOTE 5   Adapted from ISO 9000:2005, definition 3.9.1.