

Redline version
compares second edition
to first edition



Guidelines for auditing management systems

Lignes directrices pour l'audit des systèmes de management

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Reference number
ISO 19011:redline:2014(E)

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DISCLAIMER

This Redline version provides you with a quick and easy way to compare the main changes between this edition of the standard and its previous edition. It doesn't capture all single changes such as punctuation but highlights the modifications providing customers with the most valuable information. Therefore it is important to note that this Redline version is not the official ISO standard and that the users must consult with the clean version of the standard, which is the official standard, for implementation purposes.



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Published in Switzerland

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Foreword

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 3~~Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards ~~accepted~~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 ~~members~~member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this ~~International Standard~~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 ~~jointly~~ by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*, and ~~Technical Committee ISO/TC 207, Environmental management, Subcommittee SC 2, Environmental auditing and related environmental investigations.~~

This ~~first edition of~~ ~~second edition~~ cancels and replaces the first edition (ISO 19011:2002 ~~cancels and replaces~~ ISO 10011 1:1990, ISO 10011 2:1991, which ISO 10011 3:1991, has ISO 14010:1996, been ISO 14011:1996 and technically revised ISO 14012:1996.

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

Introduction

The ~~Since ISO 9000 and the first ISO 14000 series edition~~ of International Standards emphasize the importance of audits as a management tool for monitoring and verifying the effective implementation of an organization's quality and/or environmental policy. Audits are also an essential part of conformity assessment activities such as external certification/registration and of supply chain evaluation and surveillance. ~~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 provides guidance on the management of audit programmes, the conduct of internal or external audits of quality and/or environmental management systems, as well as on the competence and evaluation of auditors. It is intended to apply to a broad range of potential users, including auditors, organizations implementing quality and/or environmental management systems, and organizations needing to conduct audits of quality and/or environmental management systems for contractual reasons, and organizations involved in auditor certification or training, in certification/registration of management systems, in accreditation or in standardization in the area of conformity assessment 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 these guidelines can differ according to the size, 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. Throughout this International Standard, supplementary guidance or examples on specific topics are provided in the form of practical help in boxed text. In some instances, this is intended to support the use of this International Standard in small organizations.

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 of auditing on which auditing is based. These principles help the user to appreciate understand the essential nature of auditing and they are a necessary prelude to important in understanding the clauses 5, guidance 6 and set out in Clauses 5 to 7.

Clause 5 provides guidance on managing audit programmes and covers such issues as assigning responsibility for managing audit programmes, establishing and managing an audit programme, establishing the audit programme objectives, and coordinating auditing activities and providing sufficient audit team resources.

Clause 6 provides guidance on conducting audits of quality and/or environmental management systems, including the selection of audit teams, planning and conducting an audit of a management system.

Clause 7 provides guidance on relating to the competence needed by an auditor and describes a process for evaluating auditors and evaluation of management system auditors and audit teams.

Where quality and environmental management systems are implemented together, it is at the discretion of the user of this International Standard as to whether the quality management system and environmental management system audits are conducted separately or together.

Although Annex A this International Standard is applicable to the auditing of quality and/or environmental management systems, the user can consider adapting or extending the guidance provided herein illustrates the application of the guidance in Clause 7 to apply to other types of audits, including other management system audits different disciplines.

This Annex B International Standard provides only guidance, however, users can apply this to develop their own audit related requirements provides additional guidance for auditors on planning and conducting audits.

In addition, any other individual or organization with an interest in monitoring conformance to requirements, such as product specifications or laws and regulations, may find the guidance in this International Standard useful.

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 competence of quality and environmental management system auditors, 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 needing that need to conduct internal or external audits of quality and/or environmental management systems or to manage an audit programme.

The application of this International Standard to other types of audits is possible in principle, provided that special consideration is paid given to identifying the competence needed by the audit team members in such cases specific competence needed.

2 Normative references

The following normative documents contain provisions which, through references in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative documents indicated below. For undated references, the latest edition of the normative document referred to apply. Members of ISO and IEC maintain registers of currently valid International Standards. No normative references are cited. This clause is included in order to retain clause numbering identical with other ISO management system standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

ISO 14050:2002, *Environmental management — Vocabulary*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in document, the following ISO 9000 and ISO 14050 apply, unless superseded by the terms and definitions given below apply.

A term in a definition or note which is defined elsewhere in this clause is indicated by boldface followed by its entry number in parentheses. Such a boldface term may be replaced in the definition by its complete definition.

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 to entry: Internal audits, sometimes called first-party audits, are conducted by the organization itself, or on behalf of, the organization itself, for management review and other internal purposes, and may (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 smaller organizations, independence can be demonstrated by the freedom from responsibility for the activity being audited or freedom from bias and conflict of interest.

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Note 2 to entry: External audits include those ~~generally termed second~~ **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 ~~external~~ independent auditing organizations, such as **regulators or those providing registration or certification of conformity to the requirements of ISO 9001 or ISO 14001 certification.**

Note 3 to entry: When ~~a quality management system and an environmental management system~~ **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 to entry: When two or more auditing organizations cooperate to audit a single *auditee* (3.7), this is termed a joint audit.

Note 5 to entry: Adapted from ISO 9000:2005, definition 3.9.1.

3.2 audit criteria

set of policies, procedures or requirements **used as a reference against which** *audit evidence* (3.3) **is compared**

Note 1 to entry: Adapted from ISO 9000:2005, definition 3.9.3.

Note 2 to entry: ~~Audit criteria are used as a reference against which~~ If the audit criteria are legal (including statutory or regulatory) requirements, *audit evidence* (3.3) ~~is compared~~ the terms “compliant” or “non-compliant” are often used in an *audit finding* (3.4).

3.3 audit evidence

records, statements of fact or other information which are relevant to the *audit criteria* (3.2) and verifiable

Note 1 to entry: Audit evidence ~~may~~ **can** be qualitative or quantitative.

[SOURCE: ISO 9000:2005, definition 3.9.4]

3.4 audit findings

results of the evaluation of the collected *audit evidence* (3.3) against *audit criteria* (3.2)

Note 1 to entry: Audit findings ~~can~~ indicate either conformity or nonconformity ~~with audit criteria or opportunities for improvement.~~

Note 2 to entry: Audit findings can lead to the identification of opportunities for improvement or recording good practices.

Note 3 to entry: If the audit criteria are selected from legal or other requirements, the audit finding is termed compliance or non-compliance.

Note 4 to entry: Adapted from ISO 9000:2005, definition 3.9.5.

3.5 audit conclusion

outcome of an *audit* (3.1), ~~provided by the~~ *audit team* (3.9) after consideration of the audit objectives and all *audit findings* (3.4)

Note 1 to entry: Adapted from ISO 9000:2005, definition 3.9.6.

3.6 audit client

organization or person requesting an *audit* (3.1)

Note 1 to entry: ~~The audit client may~~ **In the case of internal audit, the audit client can also** be the *auditee* (3.7) or ~~any other organization which has the regulatory or contractual right to request an audit~~ the person managing the audit programme. Requests for external audit can come from sources such as regulators, contracting parties or potential clients.

Note 2 to entry: Adapted from ISO 9000:2005, definition 3.9.7.

3.7

auditee

organization being audited

[SOURCE: ISO 9000:2005, definition 3.9.8]

3.8

auditor

person ~~with the~~ who conducts *competence* (3.14) ~~to conduct an audit~~ (3.1)

3.9

audit team

one or more *auditors* (3.8) conducting an *audit* (3.1), supported if needed by *technical experts* (3.10)

Note 1 to entry: One auditor of the audit team is appointed as the audit team leader.

Note 2 to entry: The audit team may include auditors-in-training.

[SOURCE: ISO 9000:2005, definition 3.9.10]

3.10

technical expert

person who provides specific knowledge or expertise to the *audit team* (3.9)

Note 1 to entry: Specific knowledge or expertise is that which relates to the organization, the process or activity to be audited, or language or culture.

Note 2 to entry: A technical expert does not act as an *auditor* (3.8) in the audit team.

[SOURCE: ISO 9000:2005, definition 3.9.11]

3.11

observer

person who accompanies the *audit team* (3.9) but does not audit

Note 1 to entry: An observer is not a part of the *audit team* (3.9) and does not influence or interfere with the conduct of the *audit* (3.1).

Note 2 to entry: An observer can be from the *auditee* (3.7), a regulator or other interested party who witnesses the *audit* (3.1).

3.12

guide

person appointed by the *auditee* (3.7) to assist the *audit team* (3.9)

~~3.11~~ 3.13

audit programme

arrangements for a set of one or more *audits* (3.1) planned for a specific time frame and directed towards a specific purpose

Note 1 to entry: ~~An audit programme~~ Adapted from ISO 9000:2005, definition 3.9.2 ~~includes all activities necessary for planning, organizing and conducting the audits.~~

3.12

audit plan

~~description of the activities and arrangements for an~~ *audit* (3.1)

~~3.13~~ **3.14**
audit scope

extent and boundaries of an *audit* (3.1)

Note 1 to entry: The audit scope generally includes a description of the physical locations, organizational units, activities and processes, as well as the time period covered.

[SOURCE: ISO 9000:2005, definition 3.9.13]

3.15
audit plan

description of the activities and arrangements for an *audit* (3.1)

[SOURCE: ISO 9000:2005, definition 3.9.12]

3.16
risk

effect of uncertainty on objectives

Note 1 to entry: Adapted from ISO Guide 73:2009, definition 1.1.

~~3.14~~ **3.17**
competence

~~demonstrated personal attributes and demonstrated~~ ability to apply knowledge and skills **to achieve intended results**

Note 1 to entry: Ability implies the appropriate application of personal behaviour during the audit process.

3.18
conformity

fulfilment of a requirement

[SOURCE: ISO 9000:2005, definition 3.6.1]

3.19
nonconformity

non-fulfilment of a requirement

[SOURCE: ISO 9000:2005, definition 3.6.2]

3.20
management system

system to establish policy and objectives and to achieve those objectives

Note 1 to entry: A management system of an organization can include different management systems, such as a quality management system, a financial management system or an environmental management system.

[SOURCE: ISO 9000:2005, definition 3.2.2]

4 Principles of auditing

Auditing is characterized by reliance on a number of principles. These **principles should help to** make the audit an effective and reliable tool in support of management policies and controls, **by** providing information on which an organization can act **in order to** improve its performance. Adherence to these principles is a prerequisite for providing audit conclusions that are relevant and sufficient and for enabling auditors, working independently from one another, to reach similar conclusions in similar circumstances.

The ~~following principles relate~~ **guidance given in Clauses 5 to 7** ~~auditors~~ **is based on the six principles outlined below.**

~~a) **Ethical conduct:** the foundation of professionalism~~

~~Trust, integrity, confidentiality and discretion are essential to auditing.~~

~~b) **Fair presentation:** *the obligation to report truthfully and accurately*~~

~~Audit findings, audit conclusions and audit reports reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the auditee are reported.~~

~~c) **Due professional care:** *the application of diligence and judgement in auditing*~~

~~Auditors exercise care in accordance with the importance of the task they perform and the confidence placed in them by audit clients and other interested parties. Having the necessary competence is an important factor.~~

~~Further principles relate to the audit, which is by definition independent and systematic.~~

a) Integrity: the foundation of professionalism

Auditors and the person managing an audit programme should:

- perform their work with honesty, diligence, and responsibility;
- observe and comply with any applicable legal requirements;
- demonstrate their competence while performing their work;
- perform their work in an impartial manner, i.e. remain fair and unbiased in all their dealings;
- be sensitive to any influences that may be exerted on their judgement while carrying out an audit.

b) Fair presentation: the obligation to report truthfully and accurately

Audit findings, audit conclusions and audit reports should reflect truthfully and accurately the audit activities. Significant obstacles encountered during the audit and unresolved diverging opinions between the audit team and the auditee should be reported. The communication should be truthful, accurate, objective, timely, clear and complete.

c) Due professional care: the application of diligence and judgement in auditing

Auditors should exercise due care in accordance with the importance of the task they perform and the confidence placed in them by the audit client and other interested parties. An important factor in carrying out their work with due professional care is having the ability to make reasoned judgements in all audit situations.

d) Confidentiality: security of information

Auditors should exercise discretion in the use and protection of information acquired in the course of their duties. Audit information should not be used inappropriately for personal gain by the auditor or the audit client, or in a manner detrimental to the legitimate interests of the auditee. This concept includes the proper handling of sensitive or confidential information.

e) Independence: the basis for the impartiality of the audit and objectivity of the audit conclusions

Auditors ~~are~~ should be independent of the activity being audited ~~and are~~ wherever practicable, and should in all cases act in a manner that is free from bias and conflict of interest. ~~Auditors maintain an objective state of mind.~~ For internal audits, auditors should be independent from the operating managers of the function being audited. Auditors should maintain objectivity throughout the audit process to ensure that the audit findings and conclusions ~~will be~~ are based only on the audit evidence.

For small organizations, it may not be possible for internal auditors to be fully independent of the activity being audited, but every effort should be made to remove bias and encourage objectivity.

ef) **Evidence-based approach:** the rational method for reaching reliable and reproducible audit conclusions in a systematic audit process

Audit evidence ~~is~~ should be verifiable. It ~~is~~ will in general be based on samples of the information available, since an audit is conducted during a finite period of time and with finite resources. ~~The~~ An appropriate use of sampling should be applied, since this is closely related to the confidence that can be placed in the audit conclusions.

~~The guidance given in the remaining clauses of this International Standard is based on the principles set out above.~~

5 Managing an audit programme

5.1 General

An organization needing to conduct audits should establish an audit programme that contributes to the determination of the effectiveness of the auditee's management system. The audit programme can include audits considering one or more management system standards, conducted either separately or in combination.

~~An audit programme may include~~ The top management should ensure that the audit programme objectives are established and assign one or more audits, depending upon the size, nature and complexity of the organization competent persons to manage the audit programme. The extent of an audit programme should be based on the size and nature of the organization being audited, as well as on the nature, functionality, complexity and the level of maturity of the management system to be audited. ~~These audits may have a variety of objectives and may also include joint or combined audits (see Notes 3 and 4 to the definition of audit in~~ Priority should be given to allocating the audit programme resources to audit those matters of significance within the management system. These may include the key characteristics of product quality or hazards related to health and safety, or significant 3.1) environmental aspects and their control.

NOTE This concept is commonly known as risk-based auditing. This International Standard does not give further guidance on risk-based auditing.

~~An audit programme also includes all activities necessary for planning and organizing the types and number of audits, and for providing resources to conduct them~~ The audit programme should include information and resources necessary to organize and conduct its audits effectively and efficiently within the specified time frames; and can also include the following:

~~An organization may establish more than one audit programme.~~

~~The organization's top management should grant the authority for managing the audit programme.~~

~~Those assigned the responsibility for managing the audit programme should~~

a) ~~establish, implement, monitor, review and improve~~ objectives for the audit programme, and ~~and~~ individual audits;

— extent/number/types/duration/locations/schedule of the audits;

— audit programme procedures;

— audit criteria;

— audit methods;

— selection of audit teams;

— necessary resources, including travel and accommodation;

b) identify the necessary resources and ensure they are provided processes for handling confidentiality, information security, health and safety, and other similar matters.

The implementation of the audit programme should be monitored and measured to ensure its objectives have been achieved. The audit programme should be reviewed in order to identify possible improvements.

Figure 1 illustrates the process flow for the management of an audit programme.

