INTERNATIONAL STANDARD

ISO 19011

Redline version
compares Third edition to
Second edition



Guidelines for auditing management systems

Lignes directrices pour l'audit des systèmes de management

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ISO 19011:2018
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 — indicates removed graphic figure

1.x ... — Heading numbers containg modifications are highlighted in yellow in the Table of Contents

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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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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~~The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the ~~rules given in~~editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

~~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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

~~ISO 19011~~This document was prepared by ~~Technical~~Project Committee ISO/~~TC 176~~PC 302, ~~*Quality management and quality assurance*~~*Guidelines for auditing management systems*~~, Subcommittee SC 3, *Supporting technologies*~~.

This ~~second~~third edition cancels and replaces the ~~first~~second edition (ISO 19011:~~2002~~2011), which has been technically revised.

The main differences compared ~~with the first~~to the second 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~~addition of the risk-based approach to the principles of auditing;

~~— 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~~expansion of the guidance on managing an audit programme, ~~6 and 7 have been reorganized~~including audit programme risk;

— expansion of the guidance on conducting an audit, particularly the section on audit planning;

— expansion of the generic competence requirements for auditors;

— adjustment of terminology to reflect the process and not the object (“thing”);

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— additional information has been included in a new Annex B, resulting in the removal of help boxesremoval of the annex containing competence requirements for auditing specific management system disciplines (due to the large number of individual management system standards, it would not be practical to include competence requirements for all disciplines);

— the competence determination and evaluation process has been strengthened;

— illustrative examples of discipline-specific knowledge and skills have been included in a newexpansion of Annex A to provide guidance on auditing (new) concepts such as organization context, leadership and commitment, virtual audits, compliance and supply chain.

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

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Introduction

Since the ~~first~~second edition of this ~~International Standard~~document was published in ~~2002~~2011, a number of new management system standards have been published, many of which have a common structure, identical core requirements and common terms and core definitions. As a result, there is ~~now~~ a need to consider a broader ~~scope of~~approach to management system auditing, as well as providing guidance that is more generic. Audit results can provide input to the analysis aspect of business planning, and can contribute to the identification of improvement needs and activities.

~~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.~~An audit can be conducted against a range of audit criteria, separately or in combination, including but not limited to:

— requirements defined in one or more management system standards;

— policies and requirements specified by relevant interested parties;

— statutory and regulatory requirements;

— one or more management system processes defined by the organization or other parties;

— management system plan(s) relating to the provision of specific outputs of a management system (e.g. quality plan, project plan).

This document provides guidance for all sizes and types of organizations and audits of varying scopes and scales, including those conducted by large audit teams, typically of larger organizations, and those by single auditors, whether in large or small organizations. This guidance should be adapted as appropriate to the scope, complexity and scale of the audit programme.

~~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".~~This document concentrates on internal audits (first party) and ~~"~~audits conducted by ~~customers on their suppliers"~~organizations on their external providers and other external interested parties (second party). ~~While those involved in~~This document can also be useful for external audits conducted for purposes other than third party management system certification. ISO/IEC 17021-1 ~~audits follow the requirements of~~provides requirements for auditing management systems for third party certification; this document can provide useful additional ~~ISO/IEC 17021:2011, they might also find the guidance~~guidance (see Table 1~~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~~Different types of ~~ISO/IEC 17021:2011~~ audits

~~Internal auditing~~ ~~External auditing~~ ~~Supplier auditing~~ ~~Third party auditing~~

1st party audit	2nd party audit	3rd party audit
Internal audit	External provider audit	Certification and/or accreditation audit
~~Sometimes called first party audit~~	~~Sometimes called second~~Other external interested party audit	~~For legal~~Statutory, regulatory and similar ~~purposes~~~~For certification (see also the requirements in ISO/IEC 17021:2011)~~ audit

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~~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~~document, 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~~individual" and "~~persons~~individuals", "auditor" and "auditors".

This ~~International Standard~~document 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~~management system audits for contractual or regulatory reasons. Users of this ~~International Standard~~document can, however, apply this guidance in developing their own audit-related requirements.

The guidance in this ~~International Standard~~document 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~~document 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~~. The nature and complexity of the organization to be audited, as well as ~~on~~ the objectives and scope of the audits to be conducted, should also be considered.

~~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~~document adopts the combined audit 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 (sometimes known as an integrated audit).

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~~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~~This document provides guidance on ~~establishing and managing~~the management of an audit programme, ~~establishing the audit programme objectives, and coordinating auditing activities~~on the planning and conducting of management system audits, as well as on the competence and evaluation of an auditor and an audit team.

~~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.~~

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Guidelines for auditing management systems

1 Scope

This ~~International Standard~~document 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~~. These activities include the individual(s) managing the audit programme, auditors and audit teams.

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

The application of this ~~International Standard~~document 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~~There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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https://standards.iteh.ai/catalog/standards/sist/[illegible]/iso-19011-2018

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
audit
systematic, independent and documented process for obtaining ~~*audit*~~*objective evidence* (~~3.3~~3.8) and evaluating it objectively to determine the extent to which the *audit criteria* (~~3.2~~3.7) are fulfilled

Note 1 to entry: 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.~~behalf of, the organization itself.

Note 2 to entry: External audits include those generally called 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~~individuals on their behalf. Third party audits are conducted by independent auditing organizations, such as ~~regulators or~~ those providing certification/registration of conformity or governmental agencies.

~~Note 3 to entry: 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 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.~~

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[SOURCE: ISO 9000:2015, 3.13.1, modified — Note 1 to entry has been added, Note 4 to entry has been modified]

3.2
combined audit
audit (3.1) carried out together at a single *auditee* (3.13) on two or more *management systems* (3.18)

Note 1 to entry: When two or more discipline-specific management systems are integrated into a single management system this is known as an integrated management system.

[SOURCE: ISO 9000:2015, 3.13.2, modified]

3.3
joint audit
audit (3.1) carried out at a single *auditee* (3.13) by two or more auditing organizations

[SOURCE: ISO 9000:2015, 3.13.3]

3.4
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

[SOURCE: ISO 9000:2015, 3.13.4, modified — wording has been added to the definition]

3.5
audit scope
extent and boundaries of an *audit* (3.1)

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

Note 2 to entry: A virtual location is where an organization performs work or provides a service using an on-line environment allowing individuals irrespective of physical locations to execute processes.

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[SOURCE: ISO 9000:2015, 3.13.5, modified — Note 1 to entry has been modified, Note 2 to entry has been added]

3.6
audit plan
description of the activities and arrangements for an *audit* (3.1)

[SOURCE: ISO 9000:2015, 3.13.6]

~~3.2~~3.7
audit criteria
set of ~~policies, procedures or requirements~~ *requirements* (3.23) used as a reference against which ~~*audit*~~*objective evidence* (~~3.3~~3.8) is compared

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

Note ~~2~~1 to entry: If the audit criteria are legal (including statutory or regulatory) requirements, the ~~terms "compliant~~words "compliance" or "non-~~compliant~~compliance" are often used in an *audit finding* (~~3.4~~3.10).

Note 2 to entry: Requirements may include policies, procedures, work instructions, legal requirements, contractual obligations, etc.

[SOURCE: ISO 9000:2015, 3.13.7, modified — the definition has been changed and Notes to entry 1 and 2 have been added]

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~~3.3~~3.8
~~audit~~objective evidence
~~records, statements of fact or other information which are relevant to the~~data supporting the existence or *~~audit criteria~~* (3.2) ~~and verifiable~~ verity of something

Note 1 to entry: ~~Audit~~Objective evidence can be ~~qualitative or quantitative~~obtained through observation, measurement, test or by other means.

Note 2 to entry: Objective evidence for the purpose of the *audit* (3.1) generally consists of records, statements of fact, or other information which are relevant to the *audit criteria* (3.7) and verifiable.

[SOURCE: ISO 9000:~~2005, definition 3.9.4~~2015, 3.8.3]

3.9
audit evidence
records, statements of fact or other information, which are relevant to the *audit criteria* (3.7) and verifiable

[SOURCE: ISO 9000:2015, 3.13.8]

~~3.4~~3.10
audit findings
results of the evaluation of the collected *audit evidence* (~~3.3~~3.9) against *audit criteria* (~~3.2~~3.7)

Note 1 to entry: Audit findings indicate *conformity* (3.20) or *nonconformity* (3.21).

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

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

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

[SOURCE: ISO 9000:2015, 3.13.9, modified — Notes to entry 2 and 3 have been modified]

~~3.5~~3.11
audit conclusion
outcome of an *audit* (3.1), after consideration of the audit objectives and all *audit findings* (~~3.4~~3.10)

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

[SOURCE: ISO 9000:2015, 3.13.10]

~~3.6~~3.12
audit client
organization or person requesting an *audit* (3.1)

Note 1 to entry: In the case of internal audit, the audit client can also be the *auditee* (~~3.7~~3.13) or the ~~person~~individual(s) managing the audit programme. Requests for external audit can come from sources such as regulators, contracting parties or potential or existing clients.

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

[SOURCE: ISO 9000:2015, 3.13.11, modified — Note 1 to entry has been added]

~~3.7~~3.13
auditee
organization as a whole or parts thereof being audited

[SOURCE: ISO 9000:~~2005, definition 3.9.8~~2015, 3.13.12, modified]

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~~3.8~~
~~auditor~~
~~person who conducts an *audit* (3.1)~~

~~3.9~~3.14
audit team
one or more ~~*auditors* (3.8)~~persons conducting an *audit* (3.1), supported if needed by *technical experts* (~~3.10~~3.16)

Note 1 to entry: One *auditor* (3.15) of the *audit team* (3.14) is appointed as the audit team leader.

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

[SOURCE: ISO 9000:~~2005, definition 3.9.10~~2015, 3.13.14]

3.15
auditor
person who conducts an *audit* (3.1)

[SOURCE: ISO 9000:2015, 3.13.15]

~~3.10~~3.16
technical expert
<audit> person who provides specific knowledge or expertise to the *audit team* (~~3.9~~3.14)

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

Note 2 to entry: A technical expert to the *audit team* (3.14) does not act as an *auditor* (~~3.8~~3.15) ~~in the audit team~~.

[SOURCE: ISO 9000:~~2005, definition 3.9.11~~2015, 3.13.16, modified — Notes to entry 1 and 2 have been modified]

~~3.11~~3.17
observer
~~person~~individual who accompanies the *audit team* (~~3.9~~3.14) but does not ~~audit~~act as an *auditor* (3.15)

~~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).~~

[SOURCE: ISO 9000:2015, 3.13.17, modified]

~~3.12~~
~~guide~~
~~person appointed by the *auditee* (3.7) to assist the *audit team* (3.9)~~

~~3.13~~3.18
~~audit programme~~management system
~~arrangements for a~~ set of ~~one~~interrelated or ~~more *audits* (3.1) planned for a specific time frame and directed towards a specific purpose~~interacting elements of an organization to establish policies and objectives, and *processes* (3.24) to achieve those objectives

Note 1 to entry: ~~Adapted from ISO 9000:2005, definition 3.9.2.~~A management system can address a single discipline or several disciplines, e.g. quality management, financial management or environmental management.

Note 2 to entry: The management system elements establish the organization's structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives and processes to achieve those objectives.

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Note 3 to entry: The scope of a management system can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

[SOURCE: ISO 9000:2015, 3.5.3, modified — Note 4 to entry has been deleted]

3.14 3.19
audit scope risk
extent and boundaries of an effect of *audit* (3.1) uncertainty

Note 1 to entry: An effect is a deviation from the expected – positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence and likelihood.

Note 3 to entry: Risk is often characterized by reference to potential events (as defined in ISO Guide 73:2009, 3.5.1.3) and consequences (as defined in ISO Guide 73:2009, 3.6.1.3), or a combination of these.

Note 4 to entry: The audit scope generally includes a description of the physical locations, organizational units, activities and processes, as well as the time period coveredRisk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood (as defined in ISO Guide 73:2009, 3.6.1.1) of occurrence.

[SOURCE: ISO 9000:2005, definition 3.9.13 2015, 3.7.9, modified — Notes to entry 5 and 6 have been deleted]

3.15 3.20
audit plan conformity
description of the activities and arrangements for an fulfilment of a *audit* (3.1) *requirement* (3.23)

[SOURCE: ISO 9000:2005, definition 3.9.12 2015, 3.6.11, modified — Note 1 to entry has been deleted]

3.16 3.21
risk nonconformity
effect of uncertainty on objectives non-fulfilment of a *requirement* (3.23)

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

[SOURCE: ISO 9000:2015, 3.6.9, modified — Note 1 to entry has been deleted]

3.17 3.22
competence
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.

[SOURCE: ISO 9000:2015, 3.10.4, modified — Notes to entry have been deleted]

3.18 3.23
conformity requirement
fulfilment of a requirement need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the organization and interested parties that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, for example in documented information.

[SOURCE: ISO 9000:2005, definition 3.6.1 2015, 3.6.4, modified — Notes to entry 3, 4, 5 and 6 have been deleted]

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3.193.24
nonconformityprocess
non-fulfilment of a requirement set of interrelated or interacting activities that use inputs to deliver an intended result

[SOURCE: ISO 9000:2005, definition 3.6.22015, 3.4.1, modified — Notes to entry have been deleted]

3.203.25
management systemperformance
system to establish policy and objectives and to achieve those objectives measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: A management system of an organization can include different management systems, such as a quality management system, a financial management systemPerformance can relate to the management of activities, *processes* (3.24) or an environmental management system, products, services, systems or organizations.

[SOURCE: ISO 9000:2005, definition 3.2.22015, 3.7.8, modified — Note 3 to entry has been deleted]

3.26
effectiveness
extent to which planned activities are realized and planned results achieved

[SOURCE: ISO 9000:2015, 3.7.11, modified — Note 1 to entry has been deleted]

4 Principles of auditing

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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 guidance given in Clauses 5 to 7 is based on the sixseven principles outlined below.

a) Integrity: the foundation of professionalism

   Auditors and the personindividual(s) managing an audit programme should:

   — perform their work ethically, with honesty, diligence, and responsibility;

   — observe and comply with any applicable legal requirementsonly undertake audit activities if competent to do so;

   — 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.

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

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

Audit evidence should be verifiable. It ~~will~~should 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. An appropriate use of sampling should be applied, since this is closely related to the confidence that can be placed in the audit conclusions.

g) Risk-based approach: an audit approach that considers risks and opportunities

The risk-based approach should substantively influence the planning, conducting and reporting of audits in order to ensure that audits are focused on matters that are significant for the audit client, and for achieving the audit programme objectives.

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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~~audit programme should be established which can include audits ~~considering~~addressing one or more management system standards or other requirements, conducted either separately or in combination (combined audit).

The ~~top management should ensure that the audit programme objectives are established and assign one or more 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~~auditee, as well as on the nature, functionality, complexity ~~and~~, the type of risks and opportunities, and the level of maturity of the management system(s) to be audited. ~~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 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.~~

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