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Smernice za presojanje sistemov vodenja (ISO/DIS 19011:2025)

Guidelines for auditing management systems (ISO/DIS 19011:2025)

Leitfaden zur Auditierung von Managementsystemen (ISO/DIS 19011:2025)

Lignes directrices pour l'audit des systèmes de management (ISO/DIS 19011:2025)

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Guidelines for auditing management systems

Lignes directrices pour l'audit des systèmes de management

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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.

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 editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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.

This document was prepared by Project Committee ISO/PC 302, *Guidelines for auditing management systems*.

This fifth edition cancels and replaces the third edition (ISO 19011:2018), which has been technically revised.

The main differences compared to the third edition are as follows:

- expansion of guidance on remote auditing methods through the introduction of guidance contained in ISO/IEC TS 17012 *Conformity assessment - Guidelines for the use of remote auditing methods in auditing management systems*;
- expansion of [Annex A](#) to provide guidance on remote auditing methods and virtual locations.

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Introduction

Since the third edition of this document was published in 2018, several management system standards have been published in new fields. Most of them have a common structure, identical core requirements and common terms and core definitions. As a result, there is a need to consider a broader approach to management system auditing, as well as providing guidance that is more generic.

This document provides guidance which can be applied to audit a range of audit criteria (separately or in combination), including but not limited to:

- requirements defined in one or more management system standards;
- policies, processes and requirements specified by the organization or other relevant interested parties;
- statutory and regulatory requirements;
- management system plan(s) relating to the provision of specific results 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.

This document concentrates on internal audits (first party) and audits conducted by organizations on their external providers and other external interested parties (second party). This document can also be useful for external audits conducted for purposes other than third party management system certification. ISO/IEC 17021-1 provides requirements for auditing management systems for third party certification; this document can provide useful additional guidance (see [Table 1](#)).

Table 1 — Different types of audits

1 st party	2 nd party	3 rd party
Internal audit	External provider audit	Certification auditor accreditation assessment
	Other external interested party audit	Statutory, regulatory and similar audit

To simplify the readability of this document, the singular form of “management system” is preferred, but the reader can adapt the implementation of the guidance to their own situation. This also applies to the use of “individual” and “individuals”, “auditor” and “auditors”.

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

The guidance in this document can also be used for the purpose of self-declaration and can be useful to organizations involved in the training, qualification and certification of persons participating in the audit program.

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

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

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This document provides guidance on the management of an audit programme, on the planning and conducting of management system audits, as well as on the competence and evaluation of an auditor and an audit team.

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Guidelines for auditing management systems

1 Scope

This 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. These individuals include those 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 document to other types of audits is possible, provided that special consideration is given to the specific competence needed.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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:

- 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 *objective evidence* (3.8) and evaluating it objectively to determine the extent to which the *audit criteria* (3.7) are fulfilled

Note 1 to entry: Internal audits, sometimes called first party audits, are conducted by, or on 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 individuals on their behalf. Third party audits are conducted by independent auditing organizations, such as those providing certification/registration of conformity or governmental agencies.

[SOURCE: ISO 9000:2015, 3.13.1, modified — Notes to entry have 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)

[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]

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3.4

remote auditing method

method used for conducting audit activities at any place other than the location of the auditee

Note 1 to entry: Remote auditing methods can be used in combination with on-site methods to achieve a full and effective audit.

Note 2 to entry: Remote auditing methods can be used for virtual locations, i.e. where an organization performs work or provides a service using an online environment, enabling individuals to execute processes irrespective of physical locations.

[SOURCE: ISO/TS 17012:2024]

3.5

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]

3.6

audit scope

extent and boundaries of an *audit* (3.1)

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 to perform processes irrespective of physical locations.

3.7

audit plan

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

[SOURCE: ISO 9000:2015, 3.13.6]

3.8

audit criteria

set of *requirements* (3.23) used as a reference against which *objective evidence* (3.8) is compared

Note 1 to entry: If the audit criteria are legal (including statutory or regulatory) requirements, the words “compliance” or “non-compliance” are often used in an *audit finding* (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]

3.9

objective evidence

data supporting the existence or verity of something

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

[SOURCE: ISO 9000:2015, 3.8.3]

3.10

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]

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3.11 audit findings

results of the evaluation of the collected *audit evidence* (3.9) against *audit criteria* (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: In English when the audit criteria are selected from statutory requirements or regulatory requirements, the audit finding is termed compliance or non-compliance.

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

3.12 audit conclusion

result of an *audit* (3.1), after consideration of the audit objectives and all *audit findings* (3.10)

[SOURCE: ISO 9000:2015, 3.13.10]

3.13 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* (3.13) or the individual(s) managing the *audit programme* (3.4). Requests for external audit can come from sources such as regulatory authorities, contracting parties or potential or existing clients.

3.14 auditee

organization as a whole or parts thereof being audited

[SOURCE: ISO 9000:2015, 3.13.12, modified]

3.15 audit team

one or more persons conducting an *audit* (3.1), supported if needed by *technical experts* (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 9000:2015, 3.13.14]

3.16 auditor

person who conducts an *audit* (3.1)

[SOURCE: ISO 9000:2015, 3.13.15]

3.17 technical expert

<audit> person who provides specific knowledge or expertise to the *audit team* (3.14)

Note 1 to entry: Specific knowledge or expertise relates to the organization, the 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* (3.15).

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

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3.18

observer

individual who accompanies the *audit team* (3.14) but does not act as an *auditor* (3.15) nor a *technical expert* (3.16)

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

3.19

management system

set of interrelated or interacting elements of an organization to establish policies and objectives, and *processes* (3.24) to achieve those objectives

Note 1 to entry: 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.

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]

3.20

risk

effect of 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 and consequences, or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.

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

3.21

conformity

fulfilment of a *requirement* (3.23)

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

3.22

nonconformity

non-fulfilment of a *requirement* (3.23)

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

3.23

competence

ability to apply knowledge and skills to achieve intended results

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

3.24

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.