

JUHTIMISSÜSTEEMI AUDITEERIMISE JUHISED

Guidelines for auditing management systems (ISO 19011:2018)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 19011:2018 sisaldab Euroopa standardi EN ISO 19011:2018 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 19011:2018 consists of the English text of the European standard EN ISO 19011:2018.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 04.07.2018.	Date of Availability of the European standard is 04.07.2018.
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ICS 03.100.70, 03.120.20

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EUROPEAN STANDARD

EN ISO 19011

NORME EUROPÉENNE

EUROPÄISCHE NORM

July 2018

ICS 03.100.70; 03.120.20

Supersedes EN ISO 19011:2011

English Version

Guidelines for auditing management systems (ISO 19011:2018)

Lignes directrices pour l'audit des systèmes de management (ISO 19011:2018)

Leitfaden zur Auditierung von Managementsystemen (ISO 19011:2018)

This European Standard was approved by CEN on 18 June 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 19011:2018) has been prepared by Technical Committee ISO/PC 302 "Guidelines for auditing management systems" in collaboration with CCMC.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2019, and conflicting national standards shall be withdrawn at the latest by January 2019.

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

This document supersedes EN ISO 19011:2011.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 19011:2018 has been approved by CEN as EN ISO 19011:2018 without any modification.

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

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

- addition of the risk-based approach to the principles of auditing;
- expansion of the guidance on managing an audit programme, 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”);
- removal 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);
- expansion of [Annex A](#) to provide guidance on auditing (new) concepts such as organization context, leadership and commitment, virtual audits, compliance and supply chain.

Introduction

Since the second edition of this document was published in 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 a need to consider a broader 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.

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.

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 audit	2 nd party audit	3 rd party audit
Internal audit	External provider audit	Certification and/or accreditation audit
	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 auditor training or personnel certification.

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 (sometimes known as an integrated audit).

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.

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 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 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)

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]