



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 19011:2010**  
**01-september-2010**

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**Smernice za presojanje sistemov vodenja**

Guidelines for auditing management systems

Lignes directrices pour l'audit des systèmes de management

**Ta slovenski standard je istoveten z: prEN ISO 19011**

<https://standards.iteh.ai/catalog/standards/sist/14b969e7-d458-4f57-bb73-f049fa7eb0e3/sist-en-iso-19011-2011>

**ICS:**

03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
13.020.10	Ravnanje z okoljem	Environmental management

**oSIST prEN ISO 19011:2010**

**en**



EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**DRAFT**  
**prEN ISO 19011**

June 2010

ICS 03.120.10; 13.020.10

Will supersede EN ISO 19011:2002

English Version

**Guidelines for auditing management systems (ISO/DIS  
19011:2010)**

Lignes directrices pour l'audit des systèmes de  
management (ISO/DIS 19011:2010)

Leitfaden für Audits von Managementsystemen (ISO/DIS  
19011:2010)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/SS F20.

If this draft becomes a European Standard, 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.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## Foreword

This document (prEN ISO 19011:2010) has been prepared by Technical Committee ISO/TC 176 "Quality management and quality assurance".

This document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 19011:2002.

### Endorsement notice

The text of ISO/DIS 19011:2010 has been approved by CEN as a prEN ISO 19011:2010 without any modification.

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# DRAFT INTERNATIONAL STANDARD ISO/DIS 19011

ISO/TC 176/SC 3

Secretariat: **NEN**

Voting begins on:  
**2010-06-17**

Voting terminates on:  
**2010-11-17**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

## Guidelines for auditing management systems

*Lignes directrices pour l'audit des systèmes de management*

[Revision of first edition (ISO 19011:2002)]

ICS 03.120.10; 13.020.10

## iTeh STANDARD PREVIEW

### ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

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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 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*.

ISO 19011:2011 was prepared under the auspices of the Joint Technical Coordination Group and administered by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*. Members of Working Group 16 under TC 176/SC 3 included representatives of other technical committees (e.g., TC 207, TC 34) and other interested parties for the management systems included within the scope of this standard.

This second edition of ISO 19011 cancels and replaces ISO 19011: 2002 which has been technically revised.

## 141 Introduction

142 Since the initial publication of ISO 19011 in 2002, a number of new management system standards have been  
 143 published. This has resulted in a need to consider a broader scope of management system auditing as well as  
 144 provide guidance that is more generic.

145 In 2006, ISO CASCO developed a standard with requirements for 3rd party management system certification audit  
 146 purposes in ISO/IEC 17021.

147 It is in this context that this revision of ISO 19011 provides guidance for all users, including small and medium sized  
 148 enterprises, specially concentrating on what are commonly termed internal (first party) and second party audit.

149 This International Standard does not state requirements but provides guidance on the management of audit  
 150 programmes and on the conduct of audits of management systems, as well as on the competence and evaluation of  
 151 auditors and audit teams. Users of this International Standard may, however, apply this guidance in developing their  
 152 own audit-related requirements.

153 This guidance is intended to apply to a broad range of potential users, including auditors, organizations  
 154 implementing management systems, and organizations needing to conduct audits of management systems for  
 155 contractual or regulatory reasons. It may also be used for the purpose self-declaration. It may also be useful to  
 156 organizations involved in auditor training or certification

157 The guidance in this International Standard is intended to be flexible. As indicated at various points in the text, the  
 158 use of this guidance may differ according to the size, level of maturity of an organizations' management system, the  
 159 nature and complexity of the organization to be audited, as well as the objectives and scope of the audits to be  
 160 conducted.

161 In this International Standard, Clause 4 describes the principles on which credible auditing is based. These  
 162 principles help the user to understand the essential nature of auditing and they are important to understanding the  
 163 guidance set out in Clauses 5 to 7.

164 Clause 5 provides guidance on the establishment and management of audit programmes, including establishing the  
 165 audit programme objectives, and coordinating auditing activities.

166 Clause 6 provides guidance on conducting audits of management systems.

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

169 Annex A illustrates the application of the guidance in Clause 7 to different disciplines (e.g. quality, environmental,  
 170 occupational health and safety, resilience, security, preparedness and continuity management and transportation  
 171 safety management).

172 Annex B provides examples of the evaluation of audit team competencies in various hypothetical organizations in  
 173 different sectors (e.g. aviation, event management).

174 Annex C 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 audit programmes and conducting management system audits, as well as guidance on the evaluation of competence of individuals involved in the audit process including those responsible for audit programme management, auditors and audit teams.

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

The application of this International Standard to other types of audit is possible, provided that special consideration is paid to the specific competences needed.

## 2 Normative references

Where standards or other documents have been used or referred to (e.g. for some definitions in clause 3) it was decided to include the original text in the present International standard in order to create a stand-alone document.

A bibliography at the end of this present International standard lists these documents as well as other useful source material.

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions given below apply. All efforts have been taken that these definitions should not conflict with the definitions used in other management system standards.

### 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, or on behalf of, the organization itself for management review and other internal purposes (e.g. to confirm the intended operation of the management system or to obtain information for improvement of the management system), and may 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.

**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 registration or 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.

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- 209 **3.2**  
 210 **audit criteria**  
 211 set of policies, procedures or requirements
- 212 NOTE 1 Audit criteria are used as a reference against which **audit evidence** (3.3) is compared.
- 213 NOTE 2 If the audit criteria are selected from legal or other requirements, the audit finding (3.4) is termed compliance or non-compliance.
- 214
- 215 NOTE 3 If the audit criteria are selected from standards (internal or external), the audit finding (3.4) is termed a **conformity**  
 216 (3.16) or **nonconformity** (3.17).
- 217 **3.3**  
 218 **audit evidence**  
 219 records, statements of fact or other information, which are relevant to the **audit criteria** (3.2) and verifiable
- 220 NOTE Audit evidence may be qualitative or quantitative.
- 221 **3.4**  
 222 **audit findings**  
 223 results of the evaluation of the collected **audit evidence** (3.3) against **audit criteria** (3.2)
- 224 NOTE Audit findings may indicate **conformity** (3.16), **nonconformity** (3.17), and opportunities for improvement or good  
 225 practices.
- 226 **3.5**  
 227 **audit conclusion**  
 228 outcome of an **audit** (3.1), after consideration of the audit objectives and all **audit findings** (3.4)
- 229 **3.6**  
 230 **audit client**  
 231 organization or person requesting an **audit** (3.1)
- 232 NOTE The audit client may be the **auditee** (3.7) or any other organization which has the regulatory or contractual right to  
 233 request an audit.
- 234 **3.7**  
 235 **auditee**  
 236 organization being audited
- 237 **3.8**  
 238 **auditor**  
 239 person who conducts an **audit** (3.1)
- 240 **3.9**  
 241 **audit team**  
 242 one or more **auditors** (3.8) conducting an **audit** (3.1), supported if needed by **technical experts** (3.15)
- 243 NOTE 1 One auditor of the audit team is appointed as the audit team leader.
- 244 NOTE 2 The audit team may include auditors-in-training.
- 245 **3.10**  
 246 **audit programme**  
 247 arrangements for a set of one or more **audits** (3.1) planned for a specific time frame and directed towards a  
 248 specific purpose
- 249 **3.11**  
 250 **audit plan**  
 251 description of the activities and arrangements for an **audit** (3.1)

252 **3.12**  
 253 **risk**  
 254 effect of uncertainty on objectives

255 [ISO 31000:2009, 2.1]

256 **3.13**  
 257 **audit scope**  
 258 extent and boundaries of an **audit** (3.1)

259 NOTE The audit scope generally includes a description of the physical locations, organizational units, activities and  
 260 processes, as well as the time period covered.

261 **3.14**  
 262 **competence**  
 263 ability to apply knowledge and skills to achieve intended results.

264 NOTE ability implies the appropriate application of personal behaviour during the audit process

265 **3.15**  
 266 **technical expert**  
 267 person who provides specific knowledge or expertise to the **audit team** (3.9)

268 NOTE 1 Specific knowledge or expertise is that which relates to the organization, the process or activity to be audited, or  
 269 language or culture.

270 NOTE 2 A technical expert does not act as an **auditor** (3.8) in the audit team.

271 **3.16**  
 272 **conformity**  
 273 fulfilment of a requirement

274 [ISO 9000:2005, 3.6.1] [standards.iteh.ai/catalog/standards/sist/14b969e7-d458-4f57-bb73-f049fa7eb0e3/sist-en-iso-19011-2011](https://standards.iteh.ai/catalog/standards/sist/14b969e7-d458-4f57-bb73-f049fa7eb0e3/sist-en-iso-19011-2011)

275 **3.17**  
 276 **nonconformity**  
 277 non-fulfilment of a requirement

278 [ISO 9000:2005 3.6.2]

279 **3.18**  
 280 **guide**  
 281 person appointed by the auditee to assist the audit team

## 282 **4 Principles of auditing**

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

288 The following principles relate to auditors and those who manage the audit programme(s).

289 a) **Integrity:** *the foundation of professionalism*

290 Auditors and those who manage the audit programme(s) should: