SLOVENSKI STANDARD
oSIST prEN ISO 19011:2010

01-september-2010

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

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**

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EUROPEAN STANDARD

NORME EUROPÉENNE

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**DRAFT
prEN ISO 19011**

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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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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

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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

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.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only. **Conformément aux dispositions de la Résolution du Conseil 15/1993, ce document est distribué en version anglaise seulement.**

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119 **Foreword**

120 ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO
121 member bodies). The work of preparing International Standards is normally carried out through ISO technical
122 committees. Each member body interested in a subject for which a technical committee has been established has
123 the right to be represented on that committee. International organizations, governmental and non-governmental, in
124 liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical
125 Commission (IEC) on all matters of electrotechnical standardization.

126 International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

127 The main task of technical committees is to prepare International Standards. Draft International Standards adopted
128 by the technical committees are circulated to the member bodies for voting. Publication as an International Standard
129 requires approval by at least 75 % of the member bodies casting a vote.

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

132 ISO 19011 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*,
133 Subcommittee SC 3, *Supporting technologies.*

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

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

140

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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.

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175   # Guidelines for auditing management systems
176

177   ## 1   Scope

178   This International Standard provides guidance on auditing management systems, including the principles of
179   auditing, managing audit programmes and conducting management system audits, as well as guidance on the
180   evaluation of competence of individuals involved in the audit process including those responsible for audit
181   programme management, auditors and audit teams.

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

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

186   ## 2   Normative references

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

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

191   ## 3   Terms and definitions

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

194   **3.1**
195   **audit**
196   systematic, independent and documented process for obtaining **audit evidence** (3.3) and evaluating it objectively
197   to determine the extent to which the **audit criteria** (3.2) are fulfilled

198   NOTE 1   Internal audits, sometimes called first party audits, are conducted by, or on behalf of, the organization itself for
199   management review and other internal purposes (e.g. to confirm the intended operation of the management system or to obtain
200   information for improvement of the management system), and may form the basis for an organization's self-declaration of
201   conformity. In many cases, particularly in smaller organizations, independence can be demonstrated by the freedom from
202   responsibility for the activity being audited or freedom from bias and conflict of interest.

203   NOTE 2   External audits include second and third party audits. Second party audits are conducted by parties having an
204   interest in the organization, such as customers, or by other persons on their behalf. Third party audits are conducted by
205   independent auditing organizations, such as regulators or those providing registration or certification.

206   NOTE 3   When two or more management systems of different disciplines (e.g. quality, environmental, occupational health
207   and safety) are audited together, this is termed a combined audit.

208   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-
214 compliance.

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 a**udit 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]

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: