

SLOVENSKI STANDARD oSIST prEN ISO 19011:2017

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Smernice za presojanje sistemov vodenja (ISO/DIS 19011:2017)

Guidelines for auditing management systems (ISO/DIS 19011:2017)

Leitfaden zur Auditierung von Managementsystemen (ISO/DIS 19011:2017)

Lignes directrices pour l'audit des systèmes de management (ISO/DIS 19011:2017)

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ICS:

03.100.70 Sistemi vodenja
03.120.10 Vodenje in zagotavljanje kakovosti
13.020.10 Ravnanje z okoljem

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en,fr,de

Management systems

quality assurance

Quality management and

Environmental management

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DRAFT INTERNATIONAL STANDARD ISO/DIS 19011

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Guidelines for auditing management systems

Lignes directrices pour l'audit des systèmes de management

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1 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.

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

9 The main task of technical committees is to prepare International Standards. Draft International Standards 10 adopted by the technical committees are circulated to the member bodies for voting. Publication as an 11 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.
- 14 ISO 19011 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.
- 17 The main difference compared with the second edition is as follows:
- 18 updated requirements relating to audit plans; now the output of the audit planning process.

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19 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.

- Audits can be conducted against a range of audit criteria, separately or in combination, including but not limited to:
- 26 requirements defined in one or more management system standards;
- 27 policies and requirements specified by other parties;
- 28 legal requirements;
- 29 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 users, including small and medium-sized organizations, and concentrates on internal audits (first party), and audits conducted by organizations on their external providers (second party). This document can also be useful for external audits conducted for purposes other than third party management system certification. ISO/IEC 17021-1:2015 provides requirements for auditing management systems for third party certification; however, this document can provide useful additional guidance (see Table 1).

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1 st party auditing	2 nd party auditing	3 rd party auditing
Internal auditing	External provider auditing	Certification and/or accreditation auditing
	Other external interested party auditing	Legal, regulatory and similar auditing

Table 1 — Different types of auditing

41

This document 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.

45 Organizations can operate or use more than one management system.

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 particular situation. This also applies to the use of "person" and "persons", "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 audits of management systems for contractual or regulatory reasons. Users of this document can, however, apply this guidance in developing their own audit-related requirements. 53 The guidance in this document can also be used for the purpose of self-declaration, and can be useful to 54 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 and on the nature and complexity of the organization to be audited, as well as on the objectives and scope of the audits to be conducted.

59 This document adopts the approach that when two or more management systems of different disciplines are 60 audited together, this is termed a "combined audit". Where these systems are integrated into a single 61 management system, the principles and processes of auditing are the same as for a combined audit.

62 Clause 3 sets out the key terms and definitions used in this document. All efforts have been taken to ensure 63 that these definitions do not conflict with definitions used in other standards.

- 64 In this document the following terms are also used:
- 65 -should indicates a recommendation;
- 66 -can indicates a possibility or a capability;
- 67 -may indicates a permission.

68 Clause 4 describes the principles on which auditing is based. These principles help the user to understand the 69 essential nature of auditing and are important in understanding the guidance set out in Clauses 5 to 7.

- 70 Clause 5 provides guidance on establishing and managing an audit programme, establishing the audit 71 programme objectives, and coordinating auditing activities.
- 72 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 andaudit teams.
- Annex A provides additional guidance for auditors on planning and conducting audits.

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DRAFT INTERNATIONAL STANDARD

76 Guidelines for auditing management systems

77 Guidelines for auditing management systems

78 **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 people may include the person(s) managing the audit programme, auditors and audit teams.

83 It is applicable to all organizations that need to conduct internal or external audits of management systems or 84 manage an audit programme.

The application of this document to other types of audits (including against criteria related to product services, contracts, supply chains) is possible, provided that special consideration is given to the specific competence

87 needed.

88 2 Normative references SIST EN ISO 19011:2018

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89 There are no normative references in this document.

90 **3 Terms and definitions**

- 91 For the purposes of this document, the following terms and definitions apply.
- 92 **3.1**

93 audit

94 systematic, independent and documented process for obtaining **audit evidence** (3.3) and evaluating it 95 objectively to determine the extent to which the **audit criteria** (3.2) 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.

101 NOTE 2 to entry: External audits include second and third party audits. Second party audits are conducted by parties 102 having an interest in the organization, such as customers, or by other persons on their behalf. Third party audits are

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 certification.

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.

106 NOTE 4 to entry: When two or more auditing organizations cooperate to audit a single **auditee** (3.7), this is termed a joint audit.

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108	[SOURCE: ISO 9000:2015, 3.13.1, modified — Notes 3 and 4 to entry added]
109 110 111	3.2 audit criteria set of requirements used as a reference against which audit evidence (3.3) is compared
112 113	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 (3.4).
114 115	NOTE 2 to entry: Requirements may include policies, procedures, work instructions, legal requirements, contractual obligations, etc.
116	[SOURCE: ISO 9000:2015, 3.13.7, modified, and Notes 1 and 2 to entry added]
117 118 119	3.3 audit evidence records, statements of fact or other information which are relevant to the audit criteria (3.2) and verifiable
120	NOTE to entry: Audit evidence can be qualitative or quantitative.
121	[SOURCE: ISO 9000:2015, 3.13.8, modified — Note to entry added]
122 123 124	3.4 audit findings results of the evaluation of the collected audit evidence (3.3) against audit criteria (3.2)
125	NOTE 1 to entry: Audit findings indicate conformity (3.18) or nonconformity (3.19).
126 127	NOTE 2 to entry: Audit findings can lead to the identification of risks, opportunities for improvement or recording good practices.
128 129	NOTE 3 to entry: If the audit criteria are selected from legal or other requirements, the audit finding is termed compliance or non-compliance. 3af3834c8757/sist-en-iso-19011-2018
130	[SOURCE: ISO 9000:2015, 3.13.9]
131 132 133	3.5 audit conclusion outcome of an audit (3.1), after consideration of the audit objectives and all audit findings (3.4)
134	[SOURCE: ISO 9000:2015, 3.13.10]
135 136 137	3.6 audit client organization or person requesting an audit (3.1)
138 139 140	NOTE to entry: In the case of internal audit, the audit client can also be the auditee (3.7) or the person(s) managing the audit programme. Requests for external audit can come from sources such as regulators, contracting parties or potential or existing clients.
141	[SOURCE: ISO 9000:2015, 3.13.11, modified — Note to entry added]
142 143 144	3.7 auditee organization being audited

145 [SOURCE: ISO 9000:2015, 3.13.12]

146 147 148	3.8 auditor person who conducts an audit (3.1)	
149	[SOURCE: ISO 9000:2015, 3.13.15]	
150 151 152	3.9 audit team one or more persons conducting an audit (3.1), supported if needed by technical experts (3.10)	
153	NOTE 1 to entry: One auditor (3.8) of the audit team is appointed as the audit team leader.	
154	NOTE 2 to entry: The audit team can include auditors-in-training.	
155	[SOURCE: ISO 9000:2015, 3.13.14, NOTE 2 modified]	
156 157 158	3.10 technical expert person who provides specific knowledge or expertise to the audit team (3.9)	
159 160	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.	
161	NOTE 2 to entry: A technical expert in the audit team (3.9) does not act as an auditor (3.8).	
162	[SOURCE: ISO 9000:2015, 3.13.16, Notes 1 and 2 modified]	
163 164 165 166	3.11 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 <u>SISTEN ISO 19011:2018</u>	
167	[SOURCE: ISO 9000:2015, 3.13.4, modified] 7/sist-en-iso-19011-2018	
168 169 170	3.12 audit scope extent and boundaries of an audit (3.1)	
171 172	NOTE 1 to entry: The audit scope generally includes a description of the physical and virtual locations, functions, activities and processes, as well as the time period covered.	
173 174	NOTE 2 to entry: A virtual location is where an organization performs work or provides a service using an on-line environment allowing persons irrespective of physical locations to execute processes.	
175	[SOURCE: ISO 9000:2015, 3.13.5, modified — Notes to entry added]	
176 177 178	3.13 audit plan description of the activities and arrangements for an audit (3.1)	
179	[SOURCE: ISO 9000:2015, 3.13.6]	
180 181 182	3.14 risk effect of uncertainty	
183	[SOURCE: ISO 9000:2015, 3.7.9, modified — Notes to entry have been deleted]	

184 185 186	3.15 competence ability to apply knowledge and skills to achieve intended results
187	[SOURCE: ISO 9000:2015, 3.10.4, modified — Notes to entry have been deleted]
188 189 190	3.16 conformity fulfilment of a requirement
191	[SOURCE: ISO 9000:2015, 3.6.11, modified — Note to entry has been deleted]
192 193 194	3.17 nonconformity non-fulfilment of a requirement
195	[SOURCE: ISO 9000:2015, 3.6.9, modified – Note to entry has been deleted]
196 197 198 199	3.18 management system set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives
200 201	NOTE 1 to entry: A management system can address a single discipline or several disciplines, e.g. quality management, financial management or environmental management.
202 203	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.
204 205 206	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.
207	[SOURCE: ISO 9000:2015, 3.5.3, modified, NOTE 4 to entry deleted]
208 209 210	3.19 requirement need or expectation that is stated, generally implied or obligatory
211 212	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.
213	NOTE 2 to entry: A specified requirement is one that is stated, for example in documented information.
214 215 216	3.20 process set of interrelated or interacting activities that use inputs to deliver the intended output
217 218 219	3.21 performance measurable result
220	NOTE 1 to entry: Performance can relate either to quantitative or qualitative findings.
221 222	NOTE 2 to entry: Performance can relate to the management of activities, processes (3.20), products (including services), systems or organizations.
223	3.22

224 effectiveness

extent to which planned activities are realized and planned results achieved

227 4 Principles of auditing

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.

- 233 The guidance given in Clauses 5 to 7 is based on the seven principles outlined below.
- a) Integrity: the foundation of professionalism
- Auditors and the person(s) managing an audit programme should:
- 236 perform their work with honesty, diligence, and responsibility;
- 237 observe and comply with any applicable legal requirements;
- 238 demonstrate their competence while performing their work;
- 239 perform their work in an impartial manner, i.e. remain fair and unbiased in all their dealings;
- 240 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

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Audit findings, audit conclusions and audit reporting output 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.

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. Auditors should maintain objectivity throughout the audit process to ensure that the audit findings and conclusions are based only on the audit evidence.