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Quality management systems - Guidelines for the application of ISO 9001:2015

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Systèmes de management de la qualité -- Lignes directrices pour l'application de l'ISO 9001:2015

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Quality management systems — Guidelines for the application of ISO 9001:2015

Systèmes de management de la qualité — Lignes directrices pour l'application de l'ISO 9001

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1 Foreword

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

9 The procedures used to develop this document and those intended for its further maintenance
10 are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria
11 needed for the different types of ISO documents should be noted. This document was drafted in
12 accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see
13 www.iso.org/directives).

14 Attention is drawn to the possibility that some of the elements of this document may be the
15 subject of patent rights. ISO shall not be held responsible for identifying any or all such patent
16 rights. Details of any patent rights identified during the development of the document will be in
17 the Introduction and/or on the ISO list of patent declarations received (see
18 www.iso.org/patents).

19 Any trade name used in this document is information given for the convenience of users and
20 does not constitute an endorsement.

21 For an explanation on the meaning of ISO specific terms and expressions related to conformity
22 assessment, as well as information about ISO's adherence to the World Trade Organization
23 (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL:
24 www.iso.org/iso/foreword.html.

25
26 The committee responsible for this document is Technical Committee ISO/TC 176, *Quality*
27 *management and quality assurance*, Subcommittee SC 2, *Quality systems*.

28 Introduction

29 This Technical Specification has been developed to assist users in the implementation of
30 a quality management system based on ISO 9001:2015.

31 This Technical Specification provides guidance on the requirements in ISO 9001:2015,
32 with a clause by clause correlation to Clauses 4 to 10; however, it does not provide
33 guidance on Annexes A and B.

34 This Technical Specification gives examples of what an organization can do, but it does
35 not add new requirements to ISO 9001. The examples in this Technical Specification are
36 not definitive and only represent possibilities, not all of which are necessarily suitable
37 for every organization.

38 ISO 9001:2015 contains requirements that can be objectively audited or assessed. This
39 Technical Specification includes examples, descriptions and options that aid both in the
40 implementation of a quality management system and in strengthening its relation to the
41 overall management of an organization. While the guidelines in this Technical
42 Specification are consistent with the ISO 9001 quality management system model, they
43 are not intended to provide interpretations of the requirements of ISO 9001 or be used
44 for audit or assessment purposes.

45
46 This Technical Specification can be used by organizations of all types, sizes, levels of
47 maturity and in all sectors and geographic locations. Implementation can vary based on
48 these factors.

49
50 ISO has published a number of other quality management standards and informative
51 resources which can assist the user and provide information on additional
52 implementation methods, including:

- 53 — the ISO handbook: *ISO 9001:2015 for Small Businesses – What to do ? Advice from*
54 *ISO/TC 176*
- 55 — the ISO 9001 Auditing Practices Group (APG) papers on website:
56 www.iso.org/tc176/ISO9001AuditingPracticesGroup
- 57 — public information on the ISO/TC 176/SC2 website: www.iso.org/tc176/sc02/public
- 58 — the ISO handbook: *The Integrated Use of Management System Standards*.

59

60 **Quality management systems — Guidelines for the** 61 **application of ISO 9001**

62 **1 Scope**

63 This Technical Specification provides guidance on the intent of the requirements in ISO
64 9001:2015. It is not intended to add to, subtract from, or in any way modify those requirements.

65 This Technical Specification describes the intent of individual clauses of quality management
66 systems, with possible examples of steps an organization can take to meet the requirements.

67 This Technical Specification does not prescribe mandatory approaches to implementation, or
68 provide any preferred method of interpretation.

69 **2 Normative references**

70 The following documents, in whole or in part, are normatively referenced in this document and
71 are indispensable for its application. For dated references, only the edition cited applies. For
72 undated references, the latest edition of the referenced document (including any amendments)
73 applies.

74 ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

75 ISO 9001:2015, Quality management systems — Requirements

76 **3 Terms and definitions**

77 For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

78 **4 Context of the organization**

79 **4.1 Understanding the organization and its context**

80 The intent of this requirement is to establish a good understanding of the relevant internal and
81 external issues that can affect, either positively or negatively, the organization's ability to
82 achieve the intended results of its quality management system. The organization should be
83 aware that internal and external issues can change, and therefore should be monitored and
84 reviewed on a regular basis.

85 This understanding is necessary to provide the foundation for determining key quality
86 management system elements such as the scope of the quality management system (see 4.3),
87 the processes (see 4.4), the policy (see 5.2), planning, objectives, risks and opportunities (see
88 Clause 6).

89 Information about internal and external issues can be found from many sources, such as through
90 internal documents and meetings, in the national and international press, websites, publications
91 from national statistics offices and other government departments, professional and technical
92 publications, conferences and meetings with local and state agencies, and professional
93 associations.

94 Examples of internal and external issues relevant to the organization's context can include, but
95 are not limited to:

- 96
97 a) internal issues:
98
99 1) overall performance of the organization, including financial results;
100
101 2) resource factors, including infrastructure, environment for the operation of the
102 processes, organizational knowledge;
103
104 3) human aspects such as competence of persons, organizational culture, relationships with
105 unions;
106
107 4) operational factors such as process, production or delivery capabilities, performance of
108 the quality management system, customer evaluation;
109
110 5) factors in the governance of the organization, such as rules and procedures for decision
111 making or organizational structure;
112
113 b) external issues:
114
115 1) macro-economic factors such as money exchange rates predictions, economic situation,
116 inflation forecast, credit availability;
117
118 2) social factors such as local unemployment rates, safety perception, education levels,
119 public holidays and working days;
120
121 3) political factors such as political stability, public investments, local infrastructure,
122 international trade agreements;
123
124 4) technological factors such as new sector technology, materials and equipment, patent
125 expirations, professional code of ethics;
126
127 5) competition, including the organization's market share, similar or substitute products or
128 services, market leader trends, customer growth trends, market stability;
129
130 6) factors which affect the work environment such as trade union regulations, legal and
131 statutory requirements, including environmental legislation and codes.

121 4.2 Understanding the needs and expectations of interested parties

122 The intent of this requirement is to ensure that the organization considers the requirements of
123 relevant interested parties beyond just those of the contractual customer and end user. The
124 intention is to focus on only those interested parties which are relevant to the quality
125 management system.

- 126 a) The following potential interested parties could be considered relevant, if they affect the
127 quality management system:
128 1) customers;
129 2) end users or beneficiaries;
130 3) regulators
131 4) joint venture partners;

- 132 5) franchisors
- 133 6) parent and subsidiary organizations;
- 134 7) owners, shareholders;
- 135 8) bankers;
- 136 9) external providers;
- 137 10) employees and others working on behalf of the organization;
- 138 11) legal and regulatory authorities (local, regional, state/provincial, national or
139 international);
- 140 12) trade and professional associations;
- 141 13) local community groups;
- 142 14) non-governmental organizations;
- 143 15) local neighbouring organizations/activities in the locality;
- 144 16) competitors;
- 145 b) Examples of interested party requirements include:
- 146 1) customer requirements regarding conformity, price, availability or delivery;
- 147 2) contracts which have been entered into with customer or external providers;
- 148 3) industry codes and standards;
- 149 4) agreements with community groups or non-governmental organizations;
- 150 5) legislation;
- 151 6) memoranda of understanding;
- 152 7) permits, licences or other forms of authorization;
- 153 8) orders issued by regulatory agencies;
- 154 9) treaties, conventions and protocols;
- 155 10) agreements with public authorities and customers;
- 156 11) voluntary principles or codes of practice;
- 157 12) voluntary labelling or environmental commitments;
- 158 13) obligations arising under contractual arrangements with the organization;
- 159 c) To understand the needs and expectations of interested parties, several activities can be
160 carried out:

- 161 1) the organization can collect information by, for example, the following methods:
- 162 — lobbying and networking;
- 163 — participation in relevant associations
- 164 — benchmarking;
- 165 — active survey;
- 166 — market surveillance;
- 167 — customer or user surveys;
- 168 — monitoring customer needs, expectations and satisfaction;
- 169
- 170 2) the organization could develop potential relevance criteria for interested parties by
- 171 examining, for example:
- 172 — their possible influence or impact on the organization's performance or decisions;
- 173 — their ability to generate risks and opportunities;
- 174 — their ability to be affected by the decisions or activities of the organization;
- 175 3) the criteria can then be used to determine relevant interest parties and their relevant
- 176 requirements.

177

178 The information resulting from these activities should be considered in planning (see Clause 6).

179 <https://standards.iteh.ai/catalog/standards/sist/f543f5c5-5764-4079-b5f0-d9e32040e721/iso-ts-9002-2016>

180 The organization should be aware that the relevant interested parties and their relevant

181 requirements can be dynamic, and should monitor and review them on a regular basis.

182

183 **4.3 Determining the scope of the quality management system**

184 The intent of this requirement is to ensure that when the scope is determined, it addresses

185 context-related issues (see 4.1), relevant requirements from relevant interested parties (see

186 4.2), and the products and services of the organization, without being either too broad or too

187 restricted and that the applicability of each requirement is correctly evaluated.

188 The scope should also take into account the organization's products and services, considering

189 such issues as:

- 190 a) the infrastructure of the quality management system,
- 191 b) the organization's different sites and activities;
- 192 c) which processes are externally provided;
- 193 d) commercial policies and strategies;
- 194 e) outsourcing;

195 f) centralized or externally provided activities, processes, products and services;

196 g) organizational knowledge.

197 Examples of activities to process the collected information, in order to determine the quality
198 management system scope, should include:

199 — assessment of the applicability of the requirements of ISO 9001;

200

201 — justification of any non-applicable requirement, taking into account that non-applicable
202 requirements should not affect the ability to achieve conformity of products and services;

203

204 — analysis of collected information based on the identified impacts of the organization's
205 capabilities, customer and other relevant interested parties' requirements, and legal
206 requirements;

207

208 — determination of the processes, products and services needed to ensure the conformity of its
209 products and services and the enhancement of customer satisfaction.

210 The outputs of the activities listed above should be available in a documented scope, including
211 justification of any non-applicable requirements.

212 NOTE The scope of the quality management system can differ from the scope of certification to ISO
213 9001:2015.

214 4.4 Quality management system and its processes

215 4.4.1 The intent of this clause is to determine the processes needed for the quality
216 management system. These include both operational processes (such as those needed for
217 product and service provision) and system processes (such as internal audit and management
218 review). [https://standards.iteh.ai/catalog/standards/sist/f543f5c5-5764-4079-b5f0-](https://standards.iteh.ai/catalog/standards/sist/f543f5c5-5764-4079-b5f0-dac320404e72/sist-ts-iso-ts-9002-2016)
219 [dac320404e72/sist-ts-iso-ts-9002-2016](https://standards.iteh.ai/catalog/standards/sist/f543f5c5-5764-4079-b5f0-dac320404e72/sist-ts-iso-ts-9002-2016)

220 a) A process:

221 1) is a set of interrelated or interacting activities;

222 2) transforms inputs into intended results;

223 3) has built-in controls and checks of performance and promotes improvement.

224 b) Inputs and outputs can be tangible (e.g. materials, components or equipment) or intangible
225 (e.g. data, information or knowledge).

226 c) Inputs such as the following should be considered:

227

228 1) defined quality management system scope;

229 2) list of products and services;

230 3) list of sites and production lines processes;

231 4) capabilities;

232 5) performance indicators such as:

- 233 — service response time; service outage trends;
- 234 — throughput rates;
- 235 — defect rates; re-work costs; warranty costs;
- 236 6) risks and opportunities identified (see 6.1);
- 237 7) organization charts;
- 238
- 239 d) The bullet list in 4.4.1 of ISO 9001, which details activities to process input information, is
240 considered to be clear without further clarification.
- 241
- 242 e) The organization should refer to 0.3 of ISO 9001 and to the quality management principles in
243 ISO 9000 for further information about the process approach. It is advisable to refer to 0.3.3
244 and Annex A4 of ISO 9001 for a better understanding of risk-based thinking.
- 245
- 246 f) When addressing risks and opportunities, the organization should use risk-based thinking to
247 establish, implement, maintain and improve the quality management system and its
248 associated processes, to:
- 249 1) decide how risk (positive or negative) is addressed in the design of processes to improve
250 process outputs and prevent undesirable results;
- 251 2) improve the effectiveness of the management system;
- 252 3) maintain and manage a system that inherently addresses risk and delivers objectives.
- 253 g) The outputs of the activities listed above can include, for example:
- 254 1) process flow maps (sequences, interrelationships and authorities or responsibilities,
255 risks and defined criteria);
- 256 2) quality management system performance data;
- 257 3) variation control;
- 258 4) indicators.

259 Further guidance on the process approach and risk-based thinking is available at
260 www.iso.org/tc176/sc02/public.

261

262 **4.4.2** The intent of this requirement is to ensure that an assessment of documented
263 information is made by the organization to adequately control the operation of its processes and
264 the performance of its quality management system.

265 It is up to the organization to specify the different types of documented information needed to
266 support the operation of the processes and the quality management system performance. By
267 assessing its own needs and applying risk-based thinking, the organization should consider its
268 size, activity, type of products or services, complexity of its processes, resources etc., as well of
269 the potential consequences of nonconformities.

270