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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 9001:2015

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ISO/TC 176/SC 2/WG 24

Secretariat: BSI

# 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

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.

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 with editorial rules of the ISO/IEC Directives, 12 accordance the Part 2 (see 13 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
- 17 the Introduction and/or on the ISO list of patent declarations received (see 18 www.iso.org/patents).
- Any trade name used in this document is information given for the convenience of users anddoes 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 <u>SIST-TS ISO/TS 9002:2016</u>
- 26 The committee responsible for this document is Technical Committee ISO/TC 176, *Quality* 22010 27 *management and quality assurance*, Subcommittee SC 2, *Quality systems*.

### Introduction 28

29 This Technical Specification has been developed to assist users in the implementation of

a quality management system based on ISO 9001:2015. 30

This Technical Specification provides guidance on the requirements in ISO 9001:2015, 31

32 with a clause by clause correlation to Clauses 4 to 10; however, it does not provide

33 guidance on Annexes A and B.

This Technical Specification gives examples of what an organization can do, but it does 34

- not add new requirements to ISO 9001. The examples in this Technical Specification are 35
- not definitive and only represent possibilities, not all of which are necessarily suitable 36
- 37 for every organization.
- 38 ISO 9001:2015 contains requirements that can be objectively audited or assessed. This Technical Specification includes examples, descriptions and options that aid both in the 39 implementation of a quality management system and in strengthening its relation to the 40 overall management of an organization. While the guidelines in this Technical 41 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
- these factors. 48
- 49

- ISO has published a number of other quality management standards and informative 50
- resources which can assist the user and provide information on additional 51 implementation methods, including: 52
- the ISO handbook: ISO 9001:2015 for Small Businesses What to do ? Advice from 53 54 *ISO/TC 176*
- the ISO 9001 Auditing Practices Group (APG) papers on website: 55
- www.iso.org/tc176/ISO9001AuditingPracticesGroup 56
- public information on the ISO/TC 176/SC2 website: www.iso.org/tc176/sc02/public 57
- the ISO handbook: The Integrated Use of Management System Standards. 58

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

#### 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

undated references, the latest edition of the referenced document (including any amendments) 72

- 73 applies.
- 74 ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

75 ISO 9001:2015, Quality management systems — Requirements

#### **3** Terms and definitions 76

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

### 4 Context of the organization TS ISO/TS 9002:2016 78

4.1 Understanding the organization and its context 79

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

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

from national statistics offices and other government departments, professional and technical 91

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:

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96 97 98	a)	int	ernal issues:
99		1)	overall performance of the organization, including financial results;
100 101		2)	resource factors, including infrastructure, environment for the operation of the processes, organizational knowledge;
102 103		3)	human aspects such as competence of persons, organizational culture, relationships with unions;
104 105		4)	operational factors such as process, production or delivery capabilities, performance of the quality management system, customer evaluation;
106 107		5)	factors in the governance of the organization, such as rules and procedures for decision making or organizational structure;
108	b)	ext	ternal issues:
109 110		1)	macro-economic factors such as money exchange rates predictions, economic situation, inflation forecast, credit availability;
111 112		2)	social factors such as local unemployment rates, safety perception, education levels, public holidays and working days;
113 114		3)	political factors such as political stability, public investments, local infrastructure, international trade agreements;
115 116		4)	technological factors such as new sector technology, materials and equipment, patent expirations, professional code of ethics;
117 h118:/		5) lard	competition, including the organization's market share, similar or substitute products or services, market leader trends, customer growth trends, market stability;
119 120		6)	factors which affect the work environment such as trade union regulations, legal and statutory requirements, including environmental legislation and codes.
121	4.2	2 Un	derstanding the needs and expectations of interested parties
122 123 124 125	rel int	evai enti	tent of this requirement is to ensure that the organization considers the requirements of nt interested parties beyond just those of the contractual customer and end user. The on is to focus on only those interested parties which are relevant to the quality rement system.
126 127	a)		e following potential interested parties could be considered relevant, if they affect the ality management system:
128		1)	customers;
129		2)	end users or beneficiaries;
130		3)	regulators
131		4)	joint venture partners;

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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;
138 139		11) legal and regulatory authorities (local, regional, state/provincial, national or 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; <b>iTeh Standards</b>
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; <u>T-TS ISO/TS 9002:2016</u>
https:// 149		<ul> <li>dards, itch.ai/catalog/standards/sist/f543 f5c5-5764-4079-b5f0-dac320404e72/sist-ts-iso-ts-9002-2016</li> <li>agreements with community groups or non-governmental organizations;</li> </ul>
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;
159 160	c)	To understand the needs and expectations of interested parties, several activities can be carried out:

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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;
169 170 171	2) the organization could develop potential relevance criteria for interested parties by 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;
175 176	3) the criteria can then be used to determine relevant interest parties and their relevant requirements.
177 178 179	The information resulting from these activities should be considered in planning (see Clause 6).
180 181 182	The organization should be aware that the relevant interested parties and their relevant distreguirements can be dynamic, and should monitor and review them on a regular basisiso-ts-90
182	4.3 Determining the scope of the quality management system
184 185 186	The intent of this requirement is to ensure that when the scope is determined, it addresses context-related issues (see 4.1), relevant requirements from relevant interested parties (see 4.2), and the products and services of the organization, without being either too broad or too

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

- The scope should also take into account the organization's products and services, consideringsuch issues as:
- a) the infrastructure of the quality management system,
- b) the organization's different sites and activities;
- 192 c) which processes are externally provided;
- 193 d) commercial policies and strategies;
- 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 quality198 management system scope, should include:

- 199 assessment of the applicability of the requirements of ISO 9001;
- justification of any non-applicable requirement, taking into account that non-applicable
   requirements should not affect the ability to achieve conformity of products and services;
- 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;
- 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.

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

NOTE The scope of the quality management system can differ from the scope of certification to ISO9001:2015.

## **4.4 Quality management system and its processes**

**4.4.1** The intent of this clause is to determine the processes needed for the quality management system. These include both operational processes (such as those needed for product and service provision) and system processes (such as internal audit and management review).

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220 //sta) A process: /catalog/standards/sist/f543f5c5-5764-4079-b5f0-dac320404e72/sist-ts-iso-ts-9002-2016

- 221 1) is a set of interrelated or interacting activities;
- 222 2) transforms inputs into intended results;
- 3) has built-in controls and checks of performance and promotes improvement.
- b) Inputs and outputs can be tangible (e.g. materials, components or equipment) or intangible(e.g. data, information or knowledge).
- c) Inputs such as the following should be considered:
- 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: