INTERNATIONAL STANDARD

ISO 9004

Redline version
compares Fourth edition to
Third edition

Quality management — Quality of an organization — Guidance to achieve sustained success

Management de la qualité — Qualité d'un organisme — Lignes directrices pour obtenir des performances durables

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

~~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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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

~~ISO 9004~~This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee ~~SC~~ 2, *Quality systems*.

This ~~third~~fourth edition cancels and replaces the ~~second~~third edition (ISO 9004:~~2000~~2009), which has been technically revised. The main changes compared to the previous edition are as follows:

~~Managing for the sustained success of an organization is a major change in focus for ISO 9004, leading to substantial changes to its structure and contents.~~

— alignment with the concepts and terminology of ISO 9000:2015 and ISO 9001:2015;

— focus on the concept of "quality of an organization";

— focus of the concept of "identity of an organization".

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Introduction

This ~~International Standard~~document provides guidance ~~to support the achievement of sustained success for any organization~~for organizations to achieve sustained success in a complex, demanding and ever-changing environment, ~~by a quality management approach~~with reference to the quality management principles described in ISO 9000:2015. Where they are applied collectively, quality management principles can provide a unifying basis for an organization's values and strategies.

While ISO 9001:2015 focuses on providing confidence in an organization's products and services, this document focuses on providing confidence in the organization's ability to achieve sustained success.

~~The sustained success of an organization is achieved by its~~Top management's focus on the organization's ability to meet the needs and expectations of ~~its~~ customers and other ~~interested parties, over the long term and in a balanced way. Sustained success can be achieved by the effective management of the organization, through awareness of the organization's environment, by learning, and by the appropriate application of either improvements, or innovations, or both~~relevant interested parties provides confidence in achieving sustained success. This document addresses the systematic improvement of the organization's overall performance. It includes the planning, implementation, analysis, evaluation and improvement of an effective and efficient management system.

Factors affecting an organization's success continually emerge, evolve, increase or diminish over the years, and adapting to these changes is important for sustained success. Examples include social responsibility, environmental and cultural factors, in addition to those that might have been previously considered, such as efficiency, quality and agility; taken together, these factors are part of the organization's context.

~~This International Standard promotes self-assessment as an important tool for the review of the maturity level of the organization, covering its leadership, strategy, management system, resources and processes, to identify areas of strength and weakness and opportunities for either improvements, or innovations, or both~~The ability to achieve sustained success is enhanced by managers at all levels learning about and understanding the organization's evolving context. Improvement and innovation also support sustained success.

This document promotes self-assessment and provides a self-assessment tool for reviewing the extent to which the organization has adopted the concepts in this document (see Annex A).

~~This International Standard provides a wider focus on quality management than ISO 9001, it addresses the needs and expectations of all relevant interested parties and provides guidance for the systematic and continual improvement of the organization's overall performance. An extended model of a process-based quality management system incorporating the elements~~A representation of the structure of this document, incorporating the elements essential to achieve sustained success of ~~ISO 9001 and ISO 9004 is given~~an organization as covered in this document, is presented in Figure 1.

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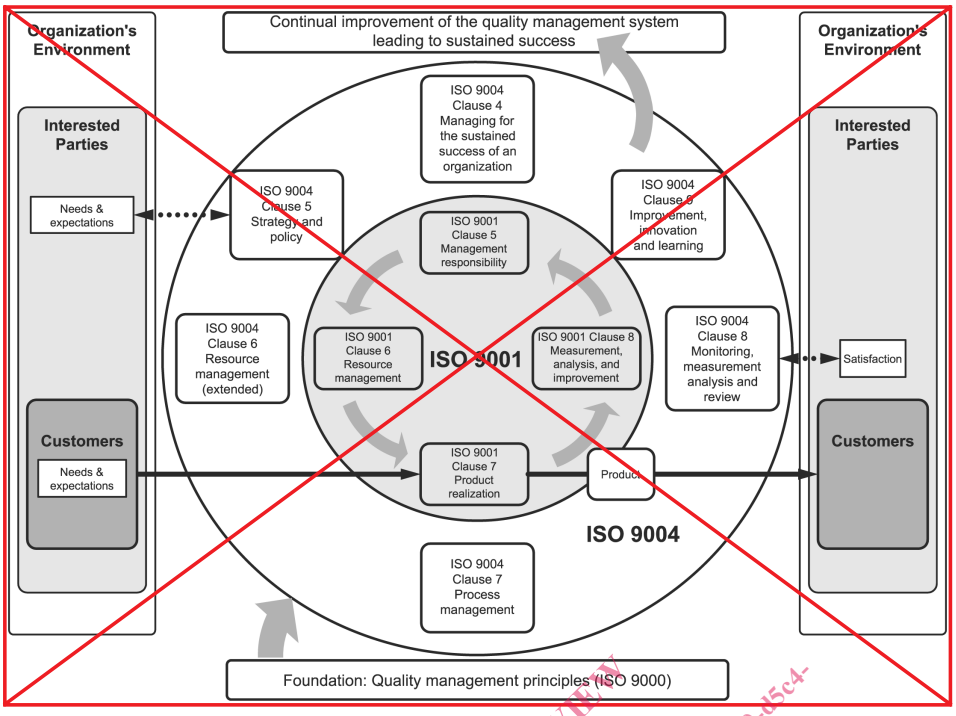

Key

Information flow

Value-adding activities

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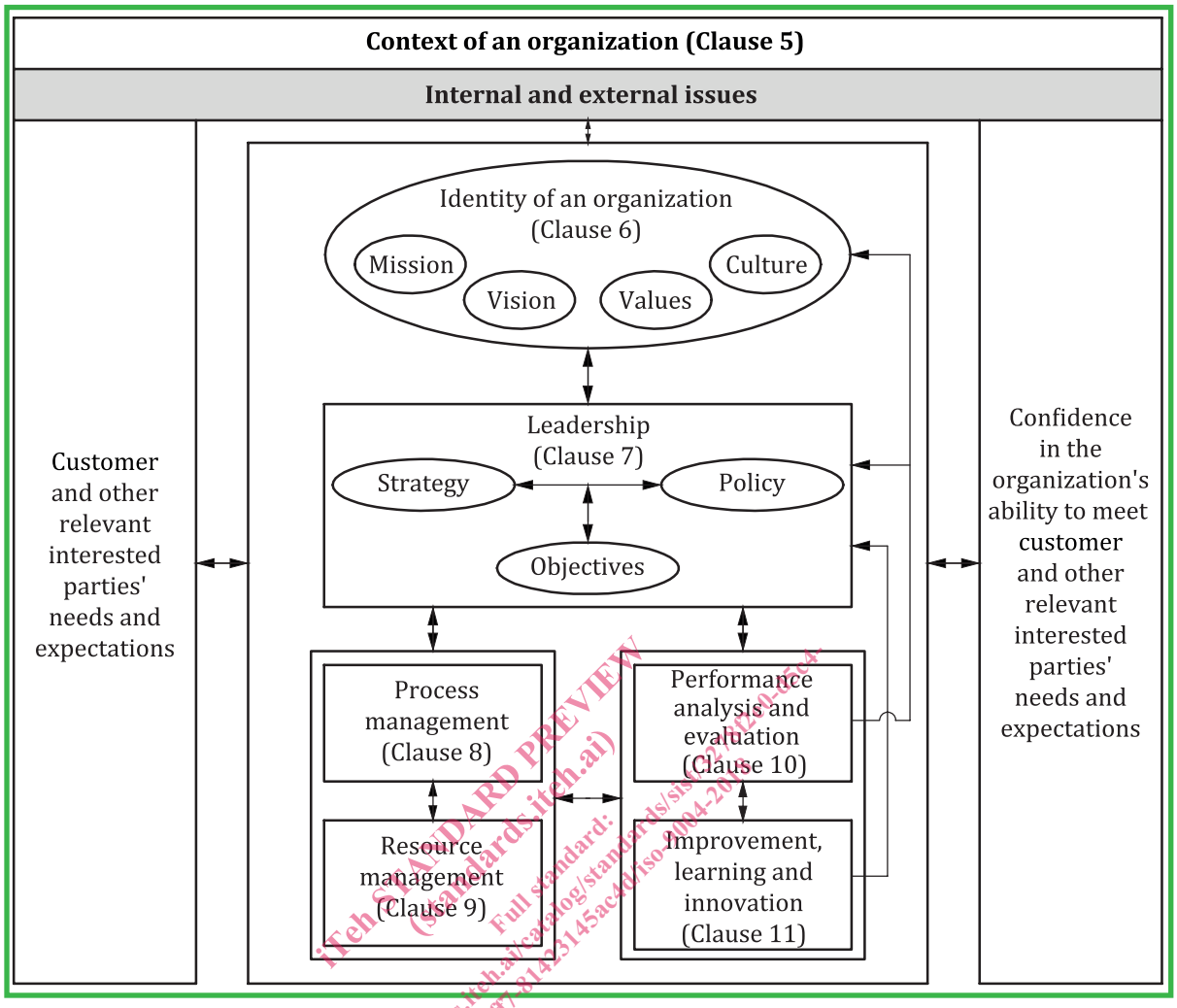

Figure 1 — ~~Extended model of a process-based quality management system~~ Representation of the structure of this document

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~~This International Standard has been developed to maintain consistency with ISO 9001 and be compatible with other management system standards. Such standards complement each other, but can also be used independently.~~

~~Annex A provides a tool for organizations to self-assess their own strengths and weaknesses, to determine their level of maturity, and to identify opportunities for improvement and innovation.~~

~~Annex B provides a description of the quality management principles that are the basis ofthe quality management standards prepared by ISO/TC 176.~~

~~Annex C gives a clause by clause correspondence between ISO 9001:2008 and this International Standard.~~

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Quality management — Quality of an organization — Guidance to achieve sustained success

1 Scope

This document gives guidelines for enhancing an organization's ability to achieve sustained success. This guidance is consistent with the quality management principles given in ISO 9000:2015.

This document provides a self-assessment tool to review the extent to which the organization has adopted the concepts in this document.

This ~~International Standard provides guidance to organizations to support the achievement of sustained success by a quality management approach. It~~document is applicable to any organization, regardless of its size, type and activity.

~~This International Standard is not intended for certification, regulatory or contractual use.~~

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2 Normative references

The following ~~referenced documents relate to the application of~~documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms and definitions

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

~~**3.1**~~
~~**sustained success**~~
~~(<organization>) result of the ability of an organization to achieve and maintain its objectives in the long term~~

~~**3.2**~~
~~**organization's environment**~~
~~combination of internal and external factors and conditions that can affect the achievement of an organization's objectives and its behaviour towards its interested parties~~

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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4 ~~Managing for the sustained success~~ Quality of an organization and sustained success

~~4.1 General~~

~~To achieve sustained success, top management should adopt a quality management approach. The organization's quality management system should be based on the principles described in Annex B. These principles describe concepts that are the foundation of an effective quality management system. To achieve sustained success, top management should apply these principles to the organization's quality management system.~~

~~The organization should develop the organization's quality management system to ensure~~

- ~~the efficient use of resources,~~
- ~~decision making based on factual evidence, and~~
- ~~focus on customer satisfaction, as well as on the needs and expectations of other relevant interested parties.~~

~~NOTE In this International Standard, the term "top management" refers to the highest level of decision making authority in an organization and the term "the organization" covers all people in an organization. This is consistent with the definitions of these terms given in ISO 9000.~~

~~4.2 Sustained success~~

~~The organization can achieve sustained success by consistently meeting the needs and expectations of its interested parties, in a balanced way, over the long term.~~

~~An organization's environment is ever-changing and uncertain, and to achieve sustained success its top management should~~

- ~~have a long-term planning perspective,~~
- ~~constantly monitor and regularly analyse the organization's environment,~~
- ~~identify all its relevant interested parties, assess their individual potential impacts on the organization's performance, as well as determining how to meet their needs and expectations in a balanced way,~~
- ~~continually engage interested parties and keep them informed of the organization's activities and plans,~~
- ~~establish mutually beneficial relationships with suppliers, partners and other interested parties,~~
- ~~make use of a wide variety of approaches, including negotiation and mediation, to balance the often competing needs and expectations of interested parties,~~
- ~~identify associated short and long-term risks and deploy an overall strategy for the organization to mitigate them,~~
- ~~anticipate future resource needs (including the competences required of its people),~~
- ~~establish processes appropriate to achieving the organization's strategy, ensuring that they are capable of responding quickly to changing circumstances,~~
- ~~regularly assess compliance with current plans and procedures, and take appropriate corrective and preventive actions,~~
- ~~ensure that people in the organization have opportunities for learning for their own benefit, as well as for maintaining the vitality of the organization, and~~

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— establish and maintain processes for innovation and continual improvement.

4.3 The organization's environment

An organization's environment will be undergoing change continually, regardless of its size (large or small), its activities and products, or its type (for profit or not-for-profit), consequently this should be monitored constantly by the organization. Such monitoring should enable the organization to identify, assess and manage the risks related to interested parties, and their changing needs and expectations.

Top management should make decisions for organizational change and innovation in a timely manner in order to maintain and improve the organization's performance.

NOTE For more information on risk management, see ISO 31000.

4.4 4.1 Interested parties, needs and expectations Quality of an organization

Interested parties are individuals and other entities that add value to the organization, or are otherwise interested in, or affected by, the activities The quality of an organization is the degree to which the inherent characteristics of the organization. Meeting fulfil the needs and expectations of interested parties contributes to the achievement of sustained success by the organization its customers and other interested parties, in order to achieve sustained success. It is up to the organization to determine what is relevant to achieve sustained success.

NOTE 1 The term "quality of an organization" is derived from the definition of "quality" given in ISO 9000:2015, 3.6.2 ("the degree to which a set of inherent characteristics of an object fulfils requirements"), and from the definition of "requirement" given in ISO 9000:2015, 3.6.4, ("needs or expectations that are stated, generally implied or obligatory"). It is distinct from the purpose of ISO 9001, which focuses on the quality of products and services in order to give confidence in the ability of an organization to provide conforming products and services and to enhance its customers' satisfaction.

NOTE 2 All references to "needs and expectations" mean "relevant needs and expectations".

NOTE 3 All references to "interested parties" mean "relevant interested parties".

NOTE 4 All references to "interested parties" include customers.

The organization should go beyond the quality of its products and services and the needs and expectations of its customers. To achieve sustained success, the organization should focus on anticipating and meeting the needs and expectations of its interested parties, with the intent of enhancing their satisfaction and overall experience.

The organization should apply all of the quality management principles (see ISO 9000:2015) to achieve sustained success. Particular attention should be given to the principles of "customer focus" and "relationship management" to meet the different needs and expectations of interested parties.

In addition, the The needs and expectations of individual interested parties are different, can be can be different, aligned to, or in conflict with those of other interested parties, or can change very quickly. The means by which the needs and expectations of interested parties are expressed and met can take a wide variety of forms, including collaboration, cooperation for example co-operation, negotiation, outsourcing, or by terminating an activity; consequently, the organization should give consideration to the interrelationships of its interested parties when addressing their needs and expectations.

Table 1 — Examples of interested parties and their needs and expectations

Interested party	Needs and expectations
Customers	Quality, price and delivery performance of products
Owners/shareholders	Sustained profitability Transparency

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