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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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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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.

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 editorial rules of the ISO/IEC Directives, Part 2 (see 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 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.

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

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

— 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 document provides guidance for organizations to achieve sustained success in a complex, demanding and ever-changing environment, 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.

Top management's focus on the organization's ability to meet the needs and expectations of customers and other 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.

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).

A representation of the structure of this document, incorporating the elements essential to achieve sustained success of an organization as covered in this document, is presented in Figure 1.

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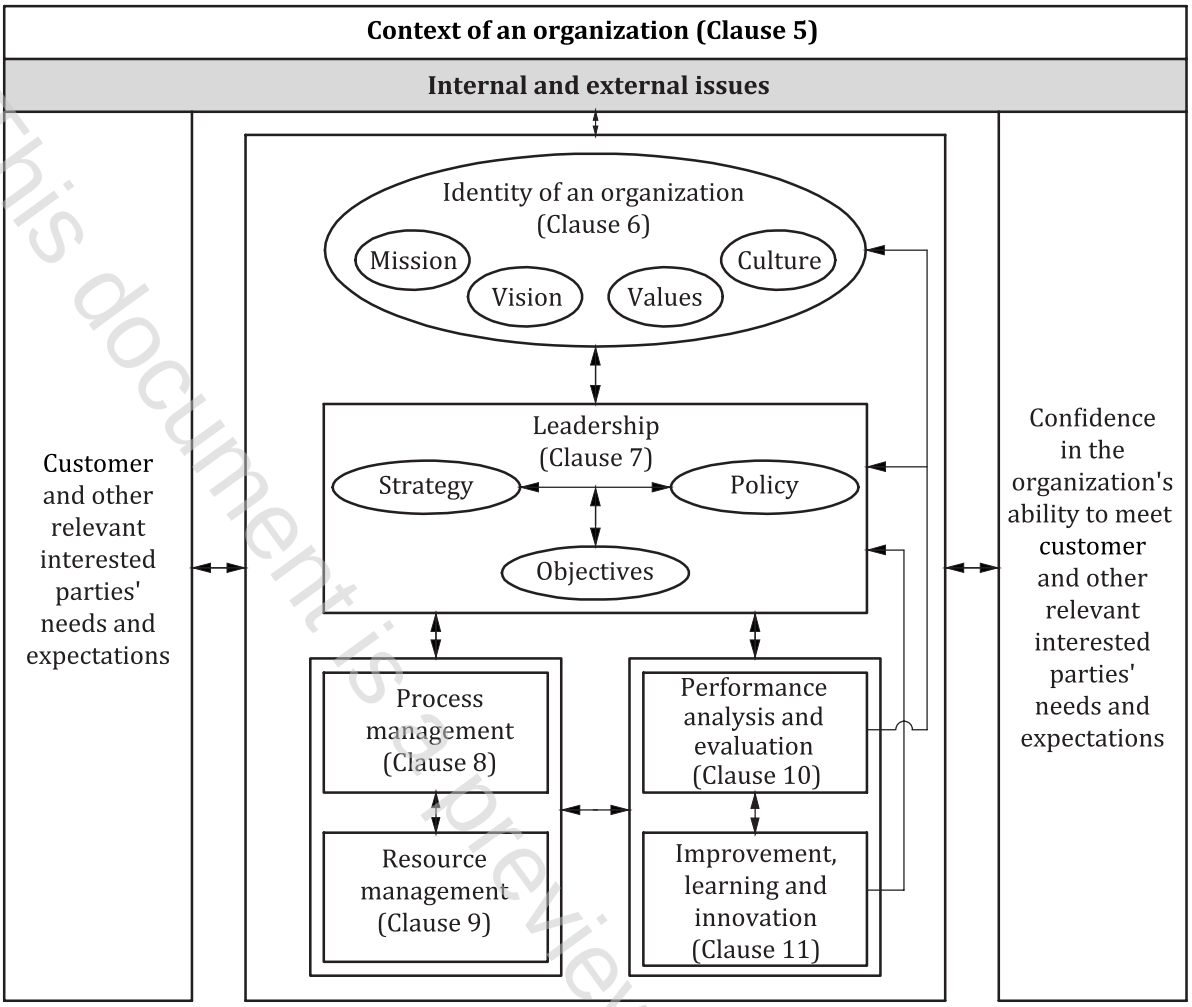

Figure 1 — Representation of the structure of this document

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

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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 document is applicable to any organization, regardless of its size, type and activity.

2 Normative references

The following 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 apply.

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/

4 Quality of an organization and sustained success

4.1 Quality of an organization

The quality of an organization is the degree to which the inherent characteristics of the organization fulfil the needs and expectations of 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.

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