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Quality management systems — Guidance for documented information

Systèmes de management de la qualité — Recommandations pour les informations documentées

PROOF/ÉPREUVE

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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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.

This second edition of ISO 10013 cancels and replaces ISO/TR 10013:2001, which has been technically revised. The main changes compared with ISO/TR 10013:2001 are as follows:

— it has been aligned with the new structure and requirements of ISO 9001:2015, notably the documentation requirements;

— the original hierarchy of documentation is no longer used but left open for the user.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

ISO 9001 requires an organization to maintain and retain documented information to support the operation of its processes and to have confidence that the processes are being carried out as planned.

Documented information is information required to be controlled and maintained by an organization and the medium on which it is contained. Documented information can be used to communicate, to provide objective evidence or for sharing knowledge.

Documented information enables the knowledge and experiences of the organization to be preserved and can generate value to support the improvement of products or services.

This document provides guidance for the development and maintenance of documented information.

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives. It is applicable to all organizations, regardless of size, complexity or business model. Its aim is to increase an organization's awareness of its duties and commitment in fulfilling the needs and expectations of its customers and interested parties, and in achieving satisfaction with its products and services.

It is important to consider the context of the organization, including the legal and regulatory framework, needs and expectations of interested parties, risks and opportunities, and strategic direction of the organization, when an organization plans what documented information to maintain and retain for its quality management system. While the adoption of a quality management system is strategic, this also applies to its documented information.

Documented information can relate to an organization's total activities or to a selected part of those activities, e.g. specified requirements depending upon the nature of products and services, processes, contractual requirements, statutory and regulatory requirements, the context of the organization itself.

It is important that the content of the documented information also conforms to the requirements of the standards they intend to satisfy, e.g. sector-specific requirements.

Organizations have been moving from paper-based systems to electronic media in the last two decades. ISO 9001 has reflected this change, replacing terminology such as "documentation, quality manual, documented procedures, and records" with "documented information." This guidance document uses the word "documented information" to refer to information that needs to be controlled by the organization and "documents" to refer to information. It also uses the word "document" as a verb in a few places.

ISO management system standards use a high-level structure to encourage the use of integrated management systems. This guidance document by its design and scope is focused on the quality management system and uses terminology from ISO 9000:2015. However, nothing prohibits its use in other management system standards.

In the previous version of this document, a hierarchy of documentation, such as a quality manual, procedures, work instructions and forms/checklists, was suggested as a way of documenting the quality management system. This document does not prescribe a particular hierarchy but reflects the ability of electronic media to organize itself in a multitude of ways. It is important to realize that while a quality manual is not required, it can still be useful, and many sector-specific standards still require "quality manuals and documented procedures".

Quality management systems — Guidance for documented information

1 Scope

This document gives guidance for the development and maintenance of the documented information necessary to support an effective quality management system, tailored to the specific needs of the organization.

This document can also be used to support other management systems, e.g. environmental or occupational health and safety management systems.

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 and the following 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/

3.1
work instruction
detailed description of how to perform tasks

EXAMPLE Detailed written descriptions, flow charts, templates, models, technical notes incorporated into drawings, specifications, equipment instruction manuals, pictures, audios and videos, checklists or combinations thereof.

Note 1 to entry: Work instructions can be documented.

Note 2 to entry: Work instructions describe any materials, equipment and documented information to be used. When relevant, work instructions include acceptance criteria.

3.2
form
documented information to be maintained and used to record data required by the quality management system

Note 1 to entry: A form becomes documented information to be retained (i.e. a record) when data are entered.

3.3
workflow
series of activities necessary to complete a task

Note 1 to entry: A workflow that is partially or completely carried out without manual interference can be referred to as an "automated workflow".

Note 2 to entry: Workflows can be documented.

4 Documented information

4.1 General

4.1.1 Structure

Documented information can be structured and created in many ways based on the needs of the organization and other factors such as leadership, intended results of the management system, context (including statutory and regulatory requirements) and interested parties.

The structure of the documented information used in the quality management system can be described in a hierarchy. This structure facilitates the distribution, maintenance and understanding of the documented information. Electronic systems provide additional choices for structuring documented information. Annex A illustrates examples of documented information structures. Smaller organizations may choose a simplified documented information structure to meet their needs.

The type and extent of the documented information needed for the quality management system should be based on an analysis of processes and can differ from one organization to another due to, for example:

a) the size of the organization and type of activities;

b) the complexity of processes and their interactions;

c) the maturity of the quality management system;

d) risks and opportunities;

e) the competence of persons;

f) statutory and regulatory requirements;

g) customer and other interested party requirements;

h) the need for evidence of results achieved;

i) the need to support accessibility and retrievability remotely.

4.1.2 Definitions

Documented information can include definitions. To enhance comprehension, the organization should consider using vocabulary that is in accordance with standard terms and definitions which are referenced in ISO 9000, in general dictionary usage or which can be specific to the organization. An organization's quality management system may use different terminology for the defined types of documented information.

4.1.3 Content

An organization's documented information should include the following:

a) the scope of the quality management system (see 4.2.1);

b) a quality policy (see 4.2.2);

c) quality objectives (see 4.2.3);

d) information that the organization determined necessary to support the operation of the quality management system and its processes, including, as applicable:

   1) a quality manual (see 4.2.4.2);

   2) organizational charts (see 4.2.4.3);

   3) process maps, process flow charts and/or process descriptions (see 4.2.4.4);

   4) procedures and work instructions (see 4.2.4.5);

   5) automated workflows (see 4.2.4.6);

   6) product and service specifications (see 4.2.4.7);

   7) internal and external communications (see 4.2.4.8);

   8) plans, schedules and lists (see 4.2.4.9);

   9) forms and checklists (see 4.2.4.10);

   10) documented information of external origin (see 4.2.4.11);

e) documented information to be retained (i.e. records) for providing evidence of results achieved (see 4.3).

Documented information can be in any type of media, such as paper, electronic, photograph or physical sample.

NOTE The advantages of electronic media are, for example:

— easier access to relevant versions including access from remote locations;

— easier control of changes, including the withdrawal of obsolete documented information;

— immediate and controlled distribution;

— retrievability and retention versus paper or other physical media.

4.1.4 Purpose

The purpose of having documented information for an organization includes:

a) communication of information;

b) evidence of achieving results or activities performed;

c) knowledge sharing;

d) knowledge preservation;

e) describing the quality management system of the organization.

4.1.5 Benefits

The benefits of having documented information for an organization include:

a) demonstrating compliance with statutory and regulatory requirements:

b) providing information for cross-functional groups so that they can better understand interrelationships;

c) communicating the organization's commitment to quality to relevant interested parties;

d) helping persons to understand their role within the organization, thus providing a basis for expectations of work performance;

e) facilitating mutual understanding between different levels in the organization;

f) providing objective evidence that specified requirements have been achieved;

g) addressing risks and opportunities to improve organizational performance, product or service conformity, and customer satisfaction;

h) providing organizational knowledge, including the basis for competency and training for persons and other relevant interested parties;

i) stating how things are to be done to consistently meet specified requirements, thus promoting controlled conditions and providing a basis for continual improvement;

j) demonstrating to interested parties the capabilities within the organization, thus providing confidence;

k) providing requirements for external providers;

l) providing a basis for auditing and evaluating the effectiveness and continuing suitability of the quality management system.

4.2 Documented information to be maintained

4.2.1 Scope of the quality management system

The scope of the quality management system should be documented based on the organization's determination of the boundaries and applicability of the quality management system. 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. The scope should state the types of products and services covered and, if required, provide justification for any requirement of the relevant quality standard that the organization determines is not applicable to the scope of its quality management system. The scope of the quality management system should be based on the nature of the organization's products and services, their operational processes, issues raised in establishing the context of the organization and relevant requirements from interested parties, the results of risk-based thinking, commercial considerations, and contractual, statutory and regulatory requirements.

4.2.2 Quality policy

The quality policy helps an organization engage its people in the culture of quality of the organization. It should be aligned with the organization's strategic direction, mission and vision. It provides a verifiable commitment to quality to relevant interested parties.

An organization can have other policies besides the quality policy relating to the quality management system.

4.2.3 Quality objectives

Quality objectives should reflect the results to be achieved by the organization with respect to its strategic direction, quality policy, risks and opportunities, and applicable requirements to the quality management system.

4.2.4 Information that the organization determined necessary to support the operation of the quality management system and its processes

4.2.4.1 General

The organization should determine the type and extent of documented information necessary to support the operation of its processes, the formats to be used and the media for communicating with users. The organization may decide what terms it uses for its documented information. While terms such as “procedures”, “work instructions” and “quality manual” are used in this document, the organization is not obliged to adopt such terminology.

4.2.4.2 Quality manual

There are many ways in which an organization can document its quality management system. Organizations can choose to use a quality manual, or a quality manual can be mandated by the organization’s external requirements. A quality manual is unique to each organization. It can provide the structure, format, content or method of presentation for documenting the quality management system and its processes for all types of organizations.

A small organization can find it appropriate to include the description of its entire quality management system within a single manual, including all the documented information it maintains. Large, multinational organizations can need manuals at different levels (e.g. the global, national or regional level) and a more complex hierarchy of documented information. If the organization chooses to implement a quality manual, it may include documented procedures or a reference to them, and a description of the processes of the quality management system and their interactions.

Information about the organization, such as name, location, context and means of communication including relevant specific terms and definitions, should be included in the quality manual. Additional information such as its line of business, a brief description of its background, history and size may also be included.

The quality manual can provide a description of the quality management system and its implementation in the organization. Descriptions of the processes and their interactions or a reference to them should be included in the manual. The processes of the organization should be designed to meet the overall objectives of the organization, its policies, context, and relevant expectations of interested parties. In large organizations, the processes can link the functional areas of the organization (see Annex A). The organization should document its specific quality management system following the sequence of the flow of the processes or any sequencing appropriate to the organization. Cross-referencing between the selected standard and the processes of the organization can be useful. The sequence and interaction of the processes within the quality management system can be documented using a process map.

NOTE 1 Manuals are also referred to as “quality manual”, “policy manual”, “reference manual”, “procedure manual” or any other suitable title.

NOTE 2 Although ISO 9001:2015 does not require a quality manual, some sector-specific standards do.

4.2.4.3 Organizational charts

Organizational charts are often graphical depictions of the roles, responsibilities and authorities within an organization. They can illustrate how roles, responsibilities and authorities flow through the organization and how different people or groups of people interact within the organization.

4.2.4.4 Process maps, process flow charts and/or process descriptions

A process map identifies the processes and visually describes the sequence and interaction of the processes in the organization. The processes can be further described using flow charts.

A process flow chart is a visual description of the process or procedure. It shows the process steps an organization performs, what triggers the process or procedure (i.e. start of the process and its input)