INTERNATIONAL STANDARD

ISO 10013

Redline version
compares ISO 10013:2021
to ISO/TR 10013:2001

Quality management systems — Guidance for documented information

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

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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 ~~whom~~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 ~~3~~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.~~

~~In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.~~

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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.

~~ISO/TR 10013~~This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.

This first edition of ISO~~/TR~~ 10013 cancels and replaces ISO/TR 10013:~~1995~~2001, ~~*Guidelines for developing quality manuals*~~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.

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Introduction

The ISO 90009001 family of International Standards requires the quality management system ofrequires an organization to be documentedmaintain 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 Technical Report promotes the adoption of the process approach when developing and implementing the quality management system and improving its effectivenessdocument provides guidance for the development and maintenance of documented information.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one of the processes directly forms the input to the nextThe 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.

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The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the 'process approach'.

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An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

An organization has flexibility in the way it chooses to documentIt 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. Each individual organization should develop that amount of documentation needed to demonstrate the effective planning, operation, control and continual improvement of itsWhile the adoption of a quality management system and its processesis strategic, this also applies to its documented information.

Quality management system documentation mayDocumented information can relate to an organization'sorganization's total activities or to a selected part of those activities, for example, e.g. specified requirements depending upon the nature of products and services, processes, contractual requirements, governing regulations or thestatutory and regulatory requirements, the context of the organization itself.

It is important that the requirements and content of the quality management system documentation address the qualitydocumented 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.

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~~The guidelines given in this Technical Report are intended to assist an organization with documenting its~~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. ~~They are not intended to be used as requirements for contractual, regulatory or certification/registration purposes~~However, nothing prohibits its use in other management system standards.

~~One aspect of a quality management system is quality planning. Quality planning documents may include managerial and operational planning, preparing the application of~~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 ~~including organizing and scheduling, and the approach by which quality objectives are to be achieved~~. 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”.

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Quality management systems — Guidance for documented information

1 Scope

This ~~Technical Report provides guidelines~~document gives guidance for the development and maintenance of the ~~documentation~~documented information necessary to ~~ensure~~support an effective quality management system, tailored to the specific needs of the organization. ~~The use of these guidelines will aid in establishing a documented system as required by the applicable quality management system standard.~~

This ~~Technical Report may~~document can also be used to ~~document management systems other than that of the~~ support other management systems~~ISO 9000 family, for example environmental management systems~~, e.g. environmental or occupational health and safety management systems.

~~NOTE When a procedure is documented, the term "written procedure" or "documented procedure" is frequently used.~~

2 Normative ~~reference~~references

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The following ~~normative document contains provisions which, through reference in this text, constitute provisions of this Technical Report. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this Technical Report are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below~~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 ~~normative document refered to applies. Members of ISO and IEC maintain registers of currently valid International Standards.~~referenced document (including any amendments) applies.

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ISO 9000:~~2000~~2015, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this ~~Technical Report~~document, the terms and definitions given in ISO 9000:2015 and the following apply. ~~An organization's quality management system may use different terminology for the defined types of documentation.~~

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 ~~instructions~~instruction
detailed ~~descriptions~~description of how to perform ~~and record~~ 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 ~~or not~~.

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Note 2 to entry: Work ~~instructions may be, for example, detailed written descriptions, flowcharts, templates, models, technical notes incorporated into drawings, specifications, equipment instruction manuals, pictures, videos, checklists, or combinations thereof. Work instructions should~~instructions describe any materials, equipment and ~~documentation~~documented information to be used. When relevant, work instructions include acceptance criteria.

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

Note 1 to entry: A form becomes ~~a record~~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 ~~Quality management system documentation~~Documented information

4.1 General

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~~The arrangement of quality management system documentation typically follows either the processes of the organization or the structure of the applicable quality standard, or a combination of both. Any other arrangement that satisfies the organization's needs may also be used.~~

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~~The structure of the documentation used in the quality management system may be described as a hierarchy. This structure facilitates the distribution, maintenance and understanding of the documentation. Annex A illustrates a typical hierarchy of quality management system documentation. The development of a hierarchy depends on the circumstances of the organization.~~

~~The extent of the quality management system documentation can differ from one organization to another due to~~

~~a) the size of the organization and type of activities,~~

~~b) the complexity of processes and their interactions, and~~

~~c) the competence of personnel.~~

~~The quality management system documentation may include definitions. The vocabulary used should be in accordance with standard definitions and terms, which are referenced in ISO 9000 or in general dictionary usage.~~

~~The quality management system documentation usually includes the following.~~

~~a) quality policy and its objectives,~~

~~b) quality manual,~~

~~c) documented procedures,~~

~~d) work instructions,~~

~~e) forms,~~

~~f) quality plans,~~

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g) specifications;

h) external documents;

i) records.

Quality management system documentation may be in any type of media, such as hard copy or electronic media.

NOTE Some advantages of using electronic media are the following:

a) appropriate personnel have access to the same up-to-date information at all times;

b) access and changes are easily made and controlled;

c) distribution is immediate and easily controlled with the option of printing hard copies;

d) there is access to documents from remote locations;

e) withdrawal of obsolete documents is simple and effective.

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.

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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.

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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).

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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.

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