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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 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 first 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.