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Sistemi vodenja kakovosti - Napotki za dokumentirane informacije

Quality management systems - Guidance for documented information

Lignes directrices pour la documentation des systèmes de management de la qualité

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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 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 drafted in accordance with the rules given in 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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This edition of ISO 10013 cancels and replaces ISO/TR 10013:2001, *Guidelines for quality management system documentation.*

This document is aligned with the new structure and requirements of ISO 9001:2015,[1] and now reflects the changes as related to the documentation requirements specifically stated in section 7.5 (Documented Information), section 4.4.2, and throughout that standard. In addition, the original hierarchy of documentation is no longer used but left open for the user. Next, ideas from within the ISO/TC 176 community have been included ([4,5]).

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 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 all 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 adoption of a quality management system is strategic, so also is its documented information.

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

It is important that the content of the documented information conforms to the requirements of the standards they intend to satisfy; for example, 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 standard 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 have adopted the high-level structure and ISO has encouraged the use of Integrated Management Systems. This guidance standard by its design and scope is focused on the quality management system and uses terminology from ISO 9001:2015.[1] However, nothing prohibits its use in other management system standards.

In the previous version of this guidance standard a hierarchy of documentation such as quality manual, procedures, work instructions, and forms/checklists were suggested as a way of documenting the quality management system. This standard does not prescribe a particular hierarchy but reflects the power of electronic media to organize itself in a multitude of ways. It is important to realize that while a quality manual is not required nothing prevents its continuing use and that many sector specific standards still require "quality manuals and documented procedures."

Quality management systems — Guidance for documented information

1 Scope

This document provides guidelines 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 may also be used to support other management systems for example environmental or occupational health and safety management systems.

This document is not intended for contractual, regulatory, or certification/registration purposes or to be used as requirements for any purpose.

2 Normative reference

The following document is referred to in the text in such a way that some or all their content constitutes guidance 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, *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 instructions
detailed descriptions of how to perform tasks

Note 1 to entry: to entry: Work instructions may or may not be documented.

Note 2 to entry: to entry: Work instructions are, for example, detailed written descriptions, flowcharts, templates, models, technical notes incorporated into drawings, specifications, equipment instruction manuals, pictures, audios and videos, checklists, or combinations thereof. 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: Note to entry: A form becomes documented information to be retained when data are entered.

3.3
workflow
series of activities necessary to complete a task.

Note 1 to entry: 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: to entry: Workflows may or may not be documented.

4 Documented information

4.1 General

4.1.1 Structure

Documented information may be structured and created in many ways based on the needs of the organization, leadership, management system intended results, context, including statutory and regulatory requirements and interested parties.

The structure of the documented information used in the quality management system may 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 documented information needed for the QMS should be based on an analysis of processes and may 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) maturity of the quality management system;

d) risks, opportunities and risk-based thinking;

e) competence of persons;

f) statutory and regulatory requirements;

g) customer and other interested party requirements;

h) need for evidence of results achieved.

It should not be the documentation that drives the processes.

4.1.2 Definitions

Documented information may include definitions. The vocabulary used shall be in accordance with standard terms and definitions, which are referenced in ISO 9000 or in general dictionary usage. 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;