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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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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Documented information	2
4.1 General.....	2
4.1.1 Structure.....	2
4.1.2 Definitions.....	2
4.1.3 Content.....	2
4.1.4 Purpose.....	3
4.1.5 Benefits.....	3
4.2 Documented information to be maintained.....	4
4.2.1 Scope of the quality management system.....	4
4.2.2 Quality policy.....	4
4.2.3 Quality objectives.....	4
4.2.4 Information that the organization determined necessary to support the operation of the quality management system and its processes.....	5
4.3 Documented information to be retained.....	9
5 Creating and updating documented information	9
5.1 Implementation.....	9
5.1.1 General.....	9
5.1.2 Use of references.....	10
5.1.3 Responsibility for creation of documented information.....	10
5.1.4 Identification and description.....	10
5.1.5 Format and media.....	10
5.1.6 Review and approval.....	11
5.2 Control of documented information.....	11
5.2.1 Availability.....	11
5.2.2 Protection.....	11
5.2.3 Distribution, access, retrieval and use.....	11
5.2.4 Storage and preservation.....	11
5.2.5 Updating documented information and control of changes.....	11
5.2.6 Retention and disposition.....	12
Annex A (informative) Examples of documented information structures	13
Bibliography	14

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".