

Guidelines for quality management system documentation

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National foreword

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Summary of pages

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TECHNICAL REPORT

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Guidelines for quality management system documentation

*Lignes directrices pour le développement de la documentation sur les
systèmes de management de la qualité*



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Foreword

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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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ISO/TR 10013 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 10013:1995, *Guidelines for developing quality manuals*.

Introduction

The ISO 9000 family of International Standards requires the quality management system of an organization to be documented.

This Technical Report promotes the adoption of the process approach when developing and implementing the quality management system and improving its effectiveness.

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 next.

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'.

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 document 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 its quality management system and its processes.

Quality management system documentation 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, processes, contractual requirements, governing regulations or the organization itself.

It is important that the requirements and content of the quality management system documentation address the quality standards they intend to satisfy.

The guidelines given in this Technical Report are intended to assist an organization with documenting its quality management system. They are not intended to be used as requirements for contractual, regulatory or certification/registration purposes.

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

