TECHNICAL REPORT

ISO/TR 10013

First edition
2001-07-15

Guidelines for quality management system documentation

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

Reference number
ISO/TR 10013:2001(E)

© ISO 2001

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2001

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

© ISO 2001 – All rights reserved

Contents

Page

Foreword iv
Introduction v
1 Scope 1
2 Normative reference 1
3 Terms and definitions 1
4 Quality management system documentation 2
4.1 General 2
4.2 Purposes and benefits 3
4.3 Quality policy and its objectives 3
4.4 Quality manual 3
4.5 Documented procedures 5
4.6 Work instructions 6
4.7 Forms 7
4.8 Quality plans 7
4.9 Specifications 7
4.10 External documents 7
4.11 Records 8
5 Process of preparing quality management system documentation 8
5.1 Responsibility for preparation 8
5.2 Method of preparation of quality management system documentation 8
5.3 Use of references 9
6 Process of approval, issue and control of quality management system documents 9
6.1 Review and approval 9
6.2 Distribution 9
6.3 Incorporation of changes 9
6.4 Issue and change control 9
6.5 Uncontrolled copies 10
Annex A Typical quality management system documentation hierarchy 11
Annex B Example of structured text work instructions 12
Bibliography 14

© ISO 2001 – All rights reserved

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 3.

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.

Attention is drawn to the possibility that some of the elements of this Technical Report may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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*.

© ISO 2001 – All rights reserved

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.

© ISO 2001 – All rights reserved

Guidelines for quality management system documentation

1 Scope

This Technical Report provides guidelines for the development and maintenance of the documentation necessary to ensure 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 be used to document management systems other than that of the ISO 9000 family, for example environmental management systems and safety management systems.

NOTE When a procedure is documented, the term “written procedure ” or “documented procedure” is frequently used.

2 Normative reference

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. 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.

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

3 Terms and definitions

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

3.1
work instructions
detailed descriptions of how to perform and record tasks

NOTE 1 Work instructions may be documented or not.

NOTE 2 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 describe any materials, equipment and documentation to be used. When relevant, work instructions include acceptance criteria.

3.2
form
document used to record data required by the quality management system

NOTE A form becomes a record when data are entered.

© ISO 2001 – All rights reserved