

Australian Standard™

**Guidelines for quality management
system documentation**

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PREFACE

This Standard was prepared by the Standards Australia Committee QR-008, Quality Systems.

This Standard is identical with, and has been reproduced, from ISO/TR 10013:2001, *Guidelines for quality management system documentation*.

The objective of this Standard is to provide 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.

As this Standard is reproduced from an International Standard, the following applies:

- (a) Its number appears on the cover and title page while the international standard number appears only on the cover.
- (b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

<i>Reference to International Standard</i>	<i>Australian/New Zealand Standard</i>
ISO	AS/NZS ISO
9000 Quality management systems— Fundamentals and vocabulary	9000 Quality management systems— Fundamentals and vocabulary

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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.

AUSTRALIAN STANDARD

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 referred 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.