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Technical Specification

Quality management systems—Guidelines for the application of ISO 9001:2015

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This Australian Technical Specification was prepared by Committee QR-008, Quality Systems. It was approved on behalf of the Council of Standards Australia on 6 April 2017. This Technical Specification was published on 17 May 2017.

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- Australian Industry Group
- Australian Institute of Petroleum
- Australian Organisation for Quality
- Australian Petroleum Production and Exploration Association
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PREFACE

This Technical Specification was prepared by the Australian members of Joint Standards Australia/Standards New Zealand Committee QR-008, Quality Systems.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Technical Specification as an Australian Technical Specification rather than an Australian/New Zealand Technical Specification.

The objective of this Technical Specification is to provide guidance on the intent of the requirements in ISO 9001:2015, with examples of possible steps an organization can take to meet the requirements. It does not add to, subtract from, or in any way modify those requirements.

This Technical Specification is identical with, and has been reproduced from ISO/TS 9002:2016, *Quality management systems—Guidelines for the application of ISO 9001:2015*.

The normative references listed in Clause 2, i.e. ISO 9000:2015 and ISO 9001:2015, were adopted as AS/NZS ISO 9000:2016 and AS/NZS ISO 9001:2016 respectively. As these are both identical adoptions, the ISO and AS/NZS ISO documents may be used interchangeably.

As this Technical Specification is reproduced from an International Technical Specification, a full point substitutes for a comma when referring to a decimal marker.

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INTRODUCTION

This document has been developed to assist users to apply the quality management system requirements of ISO 9001:2015 *Quality management systems – Requirements*.

This document provides guidance, with a clause by clause correlation to Clauses 4 to 10 of ISO 9001:2015, however it does not provide guidance on ISO 9001:2015, Annexes A and B. Where there is direct correlation between list items (i.e. bullet points) in a clause in ISO 9001:2015 and the guidance, this is indicated within the clause of this document.

This document gives examples of what an organization can do, but it does not add new requirements to ISO 9001. The examples in this document are not definitive and only represent possibilities, not all of which are necessarily suitable for every organization.

ISO 9001 contains requirements that can be objectively audited or evaluated. This document includes examples, descriptions and options that aid both in the implementation of a quality management system and in strengthening its relation to the overall management system of an organization. While the guidelines in this document are consistent with the ISO 9001 quality management system model, they are not intended to provide interpretations of the requirements of ISO 9001 or be used for audit or evaluation purposes.

As the requirements of ISO 9001 are generic, this document can be used by organizations of all types, sizes, levels of maturity and in all sectors and geographic locations. However, the way an organization applies the guidance can vary based on factors such as the size or the complexity of the organization, the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters.

Risk is the level of uncertainty inherent in a quality management system. There are risks in all systems, processes and functions. Risk-based thinking ensures these risks are determined, considered and controlled throughout the design and use of the quality management system.

Risk-based thinking has been implicit in previous editions of ISO 9001 in such requirements as determining the type and extent of control for external providers based on the effect of the product that is going to be provided, or taking corrective action based on the potential effect of an identified nonconformity.

In addition, in previous editions of ISO 9001, a clause on preventive action was included. By using risk-based thinking the consideration of risk is integral. It becomes proactive rather than reactive in preventing or reducing undesired effects through early identification and action. Preventive action is built-in when a management system is risk-based.

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its quality objectives. Some need more careful and formal planning and control than others.

There is no requirement in ISO 9001 to use formal risk management in determining and addressing risks and opportunities. An organization can choose the methods that suit its needs. IEC 31010 provides a list of risk assessment tools and techniques that can be considered, depending on the organization's context.

In some cases, an organization might have a formal risk management process in place that is required by customers or statutory and regulatory requirements. In such circumstances, the organization can adapt its formal risk management process to meet the intent of the requirements in ISO 9001 concerning risks and opportunities.

In addition to ISO 9001:2015, Annex A, ISO has published a number of other quality management standards and informative resources which can assist the user and provide information on additional implementation methods, including:

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