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

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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 which 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

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Introduction

This document has been developed to assist users to apply the quality management system requirements of ISO 9001:2015[28] *Quality management systems – Requirements*.

This document provides guidance, with a clause by clause correlation to Clauses 4 to 10 of ISO 9001:2015[28], however it does not provide guidance on ISO 9001:2015[28], Annexes A and B . Where there is direct correlation between list items (i.e. bullet points) in a clause in ISO 9001:2015[28] 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[23] 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[28], 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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— the ISO handbook: ISO 9001:2015[28] *for Small Enterprises – What to do ? Advice from ISO/TC 176*

— the ISO 9001 Auditing Practices Group (APG) papers: www.iso.org/tc176/ISO9001AuditingPracticesGroup[31]

— public information on the ISO/TC 176/SC2 website: https://committee.iso.org/tc176sc2[30]

— the ISO handbook: *The Integrated Use of Management System Standards*[29].

Additional standards and documents are listed in the Bibliography.

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

1 Scope

This document provides guidance on the intent of the requirements in ISO 9001:2015[28], 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 document does not prescribe mandatory approaches to implementation, or provide any preferred method of interpretation.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

ISO 9001:2015[28], *Quality management systems — Requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015[28] apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Context of the organization

4.1 Understanding the organization and its context

The intent of this subclause is to understand the external and internal issues that are relevant to the organization's purpose and strategic direction and that can affect, either positively or negatively, the organization's ability to achieve the intended results of its quality management system. The organization should be aware that external and internal issues can change, and therefore, should be monitored and reviewed. An organization might conduct reviews of its context at planned intervals and through activities such as management review.

Information about external and internal issues can be found from many sources, such as through internal documented information and meetings, in the national and international press, websites, publications from national statistics offices and other government departments, professional and technical publications, conferences and meetings with relevant agencies, meetings with customers and relevant interested parties, and professional associations.

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