PLUS 9001

The ISO 9000 essentials — A practical handbook for implementing the ISO 9000 family of standards

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Preface

This is the fifth edition of Plus 9001, *A practical handbook for implementing the IS0 9001 family of standards*. This edition is based on ISO 9001:2015. The primary objective of this handbook is to provide both novice and experienced quality practitioners with a concise, user-friendly guide to understanding and implementing the requirements of the ISO 9001 quality management standard. The ISO 9000 series of standards has undergone four revisions since it was initially published in 1987. ISO 9001 was revised in 1994, 2000, 2008, and, most recently, in 2015.

The first part of the handbook is made up of four subsections: "Introduction"; "The process approach"; "Conceptual overview"; and "An implementation path". The "Introduction" outlines the background of the ISO 9000 series of standards. "The process approach" introduces some of the basic concepts found in the ISO quality management system. "Conceptual overview" provides an understanding of the fundamentals associated with quality management systems (QMSs). Finally, "An implementation path" suggests an approach for QMS registration, and describes the process of conformity assessment by third-party registration bodies (registrars) and accreditation bodies.

The second part of the handbook is also made up of subsections, which are determined according to corresponding clause numbers in ISO 9001:2015. These contain:

- the actual text of ISO 9001:2015;
- guidance, providing an explanation of the intent of the ISO 9001:2015 standard;
- numerous definitions extracted from ISO 9000:2015;
- typical audit questions useful for organizations seeking to implement a QMS based on ISO 9001:2015; and
- self-diagnostic questions to be used by an organization while preparing its quality management system.

Some figures and tables were taken from the previous edition of this handbook; others were kindly provided by Pierre L'Espérance and Robert Marchand.

Layout of this handbook

All clauses of ISO 9001:2015 are reproduced in a text box.

Guidance: This section contains guidance extracted from the ISO Introduction and Support Package prepared by ISO Technical Committee 176 Subcommittee 2, or developed by members of the editorial team for this 5th edition of PLUS 9001, as well as information made available from the SCC Mirror Committee to ISO (SMC/ISO/TC 176).

Service: This section contains information relevant to the service sector, e.g., hotels, insurance companies, training providers, and governments.

Software: This section contains information relevant to computer software, in contrast to other types of intellectual software products such as music, movies, and stories.

Audit: This section contains audit questions typical of those used by third-party QMS registrars.

Definition: This section contains definitions of terms primarily from ISO 9000:2015. Notes contained in the ISO definitions are not always included in this section, but all ISO notes are included in Annex B.

Diagnostic: This section contains diagnostic questions to be considered by the organization while preparing its QMS.

Abbreviations

EDI: Electronic Data Interchange

EMS: Environmental Management System

IAF: International Accreditation Forum

IEC: International Electrotechnical Commission

ISO/TC 176: International Organization for Standardization Technical Committee 176 — Quality Management and Quality Assurance

PDCA: Plan-Do-Check-Act methodology

QMP: Quality Management Principles

QMS: Quality Management System

SCC: Standards Council of Canada

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0 Introduction

0.1 General

The ISO 9000 series of standards was developed to assist organizations of all types and sizes to implement and operate an effective quality management system (QMS). It consists of four core standards:

a) ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*, describes the fundamentals of a QMS and specifies the terminology for all standards within the ISO 9000 series.
b) ISO 9001:2015, *Quality management systems — Requirements*, specifies requirements for a QMS, where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.
c) ISO 9004:2009, *Managing for the sustained success of an organization — A quality management approach*, provides a wider focus on quality management than ISO 9001 in addressing the needs and expectations of all relevant interested parties, and provides guidance for the systematic and continual improvement of the organization's overall performance and achievement of sustained success. ISO 9004 is currently being revised, with the expectation of being published in early 2018.
d) ISO 19011:2011, *Guidelines for auditing management systems*, provides guidance on auditing any ISO management system (quality, environmental, occupational health and safety, etc.), on the management of an audit programme, on the planning and conducting of an audit of the management system, as well as on the competence and evaluation of an auditor and an audit team.

0.2 Rationale for a QMS

A QMS assists an organization in enhancing customer satisfaction. Customers require products and services with characteristics that satisfy their needs and expectations. These needs and expectations, expressed in product and service specifications, are collectively referred to as “customer requirements”. Customer requirements may be specified contractually by the customer, or may be determined by the organization itself, based on market research. In either case, the customer ultimately determines the acceptability of the product or service. Because customer needs and expectations tend to change over time, organizations are driven to continually improve their products, services and processes, since a feature/function that provided customer satisfaction in the past may be a source of customer dissatisfaction in the future.

The QMS approach encourages organizations to analyze customer requirements, define the necessary processes to contribute to development of products and services that meet the specified requirements, and to maintain those processes under control. A QMS can provide the framework for improvements to enhance the satisfaction of customers and other interested parties. It provides confidence, to the

organization and its customers, that it can provide products and services that consistently fulfil requirements.

0.3 Growth of ISO 9000 standards

The application of the ISO 9000 series of standards has expanded considerably over the years. ISO 9001 has successfully replaced national standards in the field of quality assurance around the world. Although the growth rate has levelled off in recent years, the latest survey conducted by ISO indicates that more than one million certificates have been issued in 201 countries. Both numbers clearly indicate the widespread acceptance and usage of the standards.

Certificates are only one indicator of the value that the ISO series of standards provides to its users, as many organizations have implemented ISO 9001 without seeking certification. In addition, there are a growing number of sector-specific standards that provide guidance on the application of ISO 9001 in meeting the particular requirements of an industry or business sector.

1 The process approach (overview)

ISO 9001 promotes the adoption of the process approach when developing, implementing, and improving the effectiveness of a QMS, so as to enhance customer satisfaction, by fulfilling customer requirements. For an organization to function effectively, it has to identify and manage numerous linked tasks and activities. Tasks and activities use resources, and are managed in order to enable the transformation of inputs into outputs, which can be considered to be a process. Often, the output from one process directly forms the input to the next process. Figure 1, "QMS Model with PDCA cycle", illustrates an approach for controlling the expected results from any process within the system.

The application of a system of processes within an organization, together with the identification and interaction 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.

When used within a QMS, such an approach emphasizes the importance of:

- understanding and fulfilling requirements;
- the need to consider processes in terms of added value;
- obtaining results of process performance and effectiveness; and
- improvement of processes based on objective measurement.

The model of a process-based QMS shown in Figure 1 illustrates the process linkages described in Clauses 4 to 10 of ISO 9001:2015. This illustration shows that customers and relevant interested parties play a significant role in determining requirements as inputs. Monitoring of customer satisfaction requires the ongoing evaluation of information relating to the customer's perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of ISO 9001:2015, but shows the system at a high level, not at the detailed process level.

In addition, the methodology first identified by Walter Shewart, known as "Plan-Do-Check-Act" (PDCA), can be applied to all processes. PDCA can be briefly described as:

Plan: establish the objectives and processes necessary to deliver results in accordance with customer and relevant-interested-party requirements, and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes, products, and services against policies, goals, objectives, and requirements for the products and services, and report the results.

Act: take actions to improve process performance.

This model was used to structure the ISO 9001 Standard, as can be seen from Figure 2. Since the model is linked to all seven quality management principles (QMPs), the influence of these QMPs is visible in the contents of ISO 9001, and even more so in ISO 9004. Further elaboration on the process approach is provided in Clause 0.3 of ISO 9001:2015.

Figure 1
QMS model with the PDCA cycle

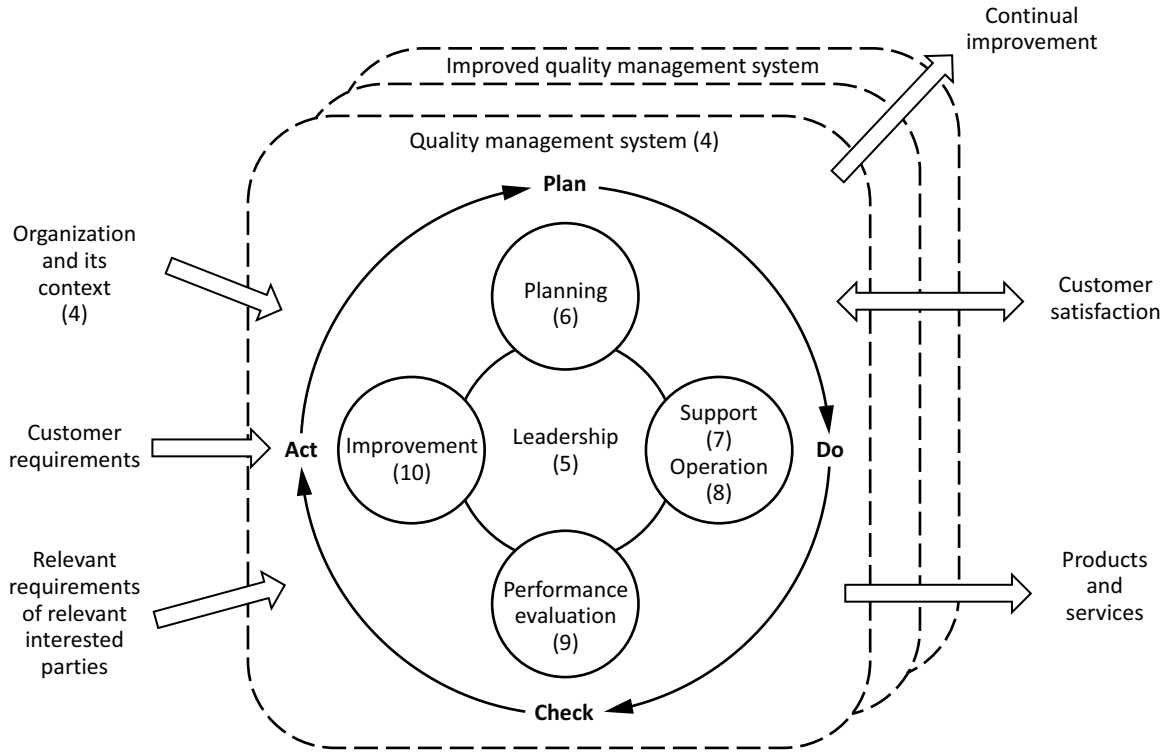
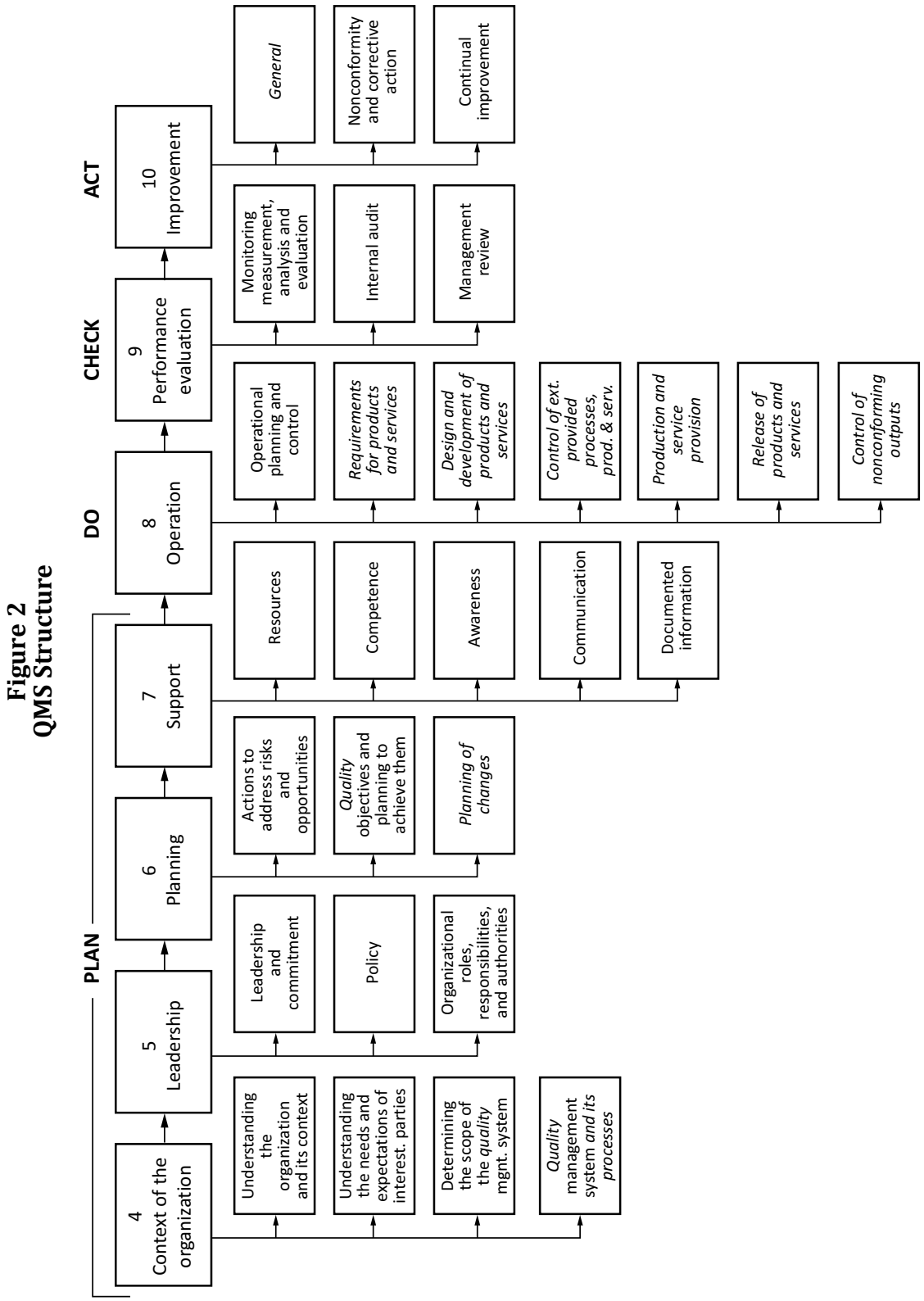


Figure 2
QMS Structure



2 Conceptual overview

2.1 Quality management principles

The following seven quality management principles (QMPs) are derived from the collective experience and knowledge of internationally recognized experts, and aimed at helping users achieve sustained organizational success. The principles are described in ISO 9000:2015, and a brochure containing further information describing how these principles form the basis for the QMS standards within the ISO 9000 series is published by ISO. This handbook describes each of the principles, and the rationale for why the principle is important, highlights the benefits derived from their use, and provides examples of typical actions managers take to improve their organizations' performance.

In order to lead and operate an organization successfully, it is necessary to direct and control it in a systematic and transparent manner. Managing an organization encompasses quality management, in coordination with other management disciplines, as an integral part of the overall business system.

Table 1
Quality management principles

• Customer focus
• Leadership
• Engagement of people
• Process approach
• Improvement
• Evidence-based decision-making
• Relationship management

1) **Customer focus:** The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

   Sustained success is achieved when an organization attracts and retains the confidence of customers and other relevant interested parties. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to the sustained success of the organization.
2) **Leadership:** Leaders at all levels establish unity of purpose and direction, and create conditions in which people are engaged in achieving the organization's quality objectives.

   Creation of unity of purpose and the direction and engagement of people enable an organization to align its strategies, policies, processes, and resources to achieve its objectives.
3) **Engagement of people:** Competent, empowered, and engaged people at all levels throughout the organization are essential to enhance the organization's capability to create and deliver value.

   In order to manage an organization effectively and efficiently, it is important to respect and involve all people at all levels. Recognition, empowerment, and enhancement of competence facilitate the engagement of people in achieving the organization's quality objectives.
4) **Process approach:** Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

   The QMS consists of interrelated processes. Understanding how results are produced by this system enables an organization to optimize the system and its performance.
5) **Improvement:** Successful organizations have an ongoing focus on improvement.

Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions, and to create new opportunities.

6) **Evidence-based decision-making:** Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

   Decision-making can be a complex process and always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause-and-effect relationships and potential unintended consequences. Facts, evidence, and data analysis lead to greater objectivity and confidence in decision-making.

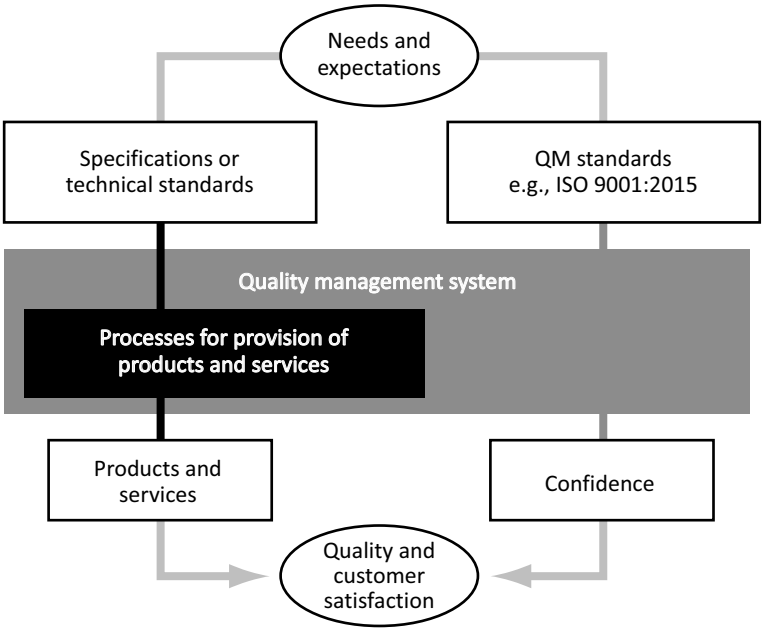
7) **Relationship management:** For sustained success, organizations manage their relationships with relevant interested parties, such as providers.

   Relevant interested parties influence the performance of an organization. Sustained success is more likely to be achieved when the organization manages relationships with all of its interested parties to optimize their impact on its performance. Relationship management with its provider and partner networks is of particular importance.

2.2 Requirements for products and services, and requirements for quality management systems

The ISO 9000 family distinguishes between requirements for QMSs and requirements for products and services. Requirements for QMSs are specified in ISO 9001. Requirements for QMSs are generic and applicable to organizations in any business, industry, or economic sector, regardless of the offered product/service category. ISO 9001 itself does not establish requirements for products or services.

Figure 3
Quality: Products, services, and confidence



Delivering a product or service that meets user requirements involves a dual approach. On the one hand, a product/service must often conform to technical specifications that address certain attributes related to performance and characteristics. On the other hand, the organization must ensure that these attributes are consistently built into or incorporated in the product/service. This dual approach is