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Introduction

This draft standard is based on European discussions in which the UK has taken an active part. Your comments on this draft are welcome and will assist in the preparation of the consequent British Standard. Comment is particularly welcome on national, legislative or similar deviations that may be necessary.

Even if this draft standard is not approved by the UK, if it receives the necessary support in Europe, the UK will be obliged to publish the official English Language text unchanged as a British Standard and to withdraw any conflicting standard.

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Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	(7)
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/ Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

DRAFT INTERNATIONAL STANDARD

ISO/DIS 9000

ISO/TC 176/SC 1

Secretariat: **ANSI**

Voting begins on:
2014-07-10

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Quality management systems — Fundamentals and vocabulary

Systèmes de management de la qualité — Principes essentiels et vocabulaire

ICS: 03.120.10;01.040.03

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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.

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.

ISO 9000 was prepared by Technical Committee ISO/TC 176, *TC Quality management and quality assurance*, Subcommittee SC 1, *SC Concepts and terminology*.

This fourth edition cancels and replaces the third edition (ISO 9000:2005).

Introduction

This International Standard provides the fundamentals and terminology of quality management systems. It is the foundation of other ISO quality management system standards and serves as the normative reference for many of them. It will help the user to understand the principles, systems model and terminology of quality management in order to more effectively and efficiently implement a quality management system and realize value from other ISO quality management system standards.

This management standard for quality makes the case for a well-defined quality management system based on a framework that integrates established quality fundamental concepts, principles, processes and resources to help organizations realize their goals. Its aim is to make top management aware of their duties and commitment in achieving their customers and stakeholders needs, expectations and satisfaction with their products and services.

The terms and definitions are arranged in conceptual order according to ISO/IEC Directives. Annex A provides information on how this works, including the set of diagrams of the concept systems that form the concept ordering. An alphabetical list is provided at the end of the document to aid location of entries.

Quality management systems — Fundamentals and vocabulary

1 Scope

This International Standard describes the fundamental concepts, principles and vocabulary of quality management, and defines related terms, which are universally applicable to the following:

- organizations seeking sustained success through the implementation of quality and other management systems;
- customers seeking confidence in organization's ability to provide satisfactory products;
- organizations seeking confidence in their supply chain that their product requirements will be met;
- those interested parties seeking to improve communication through a common understanding of the terminology used in quality management;
- organizations performing conformity assessments against the requirements of ISO 9001;
- those providing training in quality management;
- developers of related standards.

2 Quality management principles and fundamental concepts

2.1 General

The quality management concepts and principles described in this standard give management the capacity to meet challenges presented by an environment that is profoundly different from that of just a few decades ago. The context in which the 21st century organisation works is characterised by accelerated change, globalisation of markets, limited resources, and the emergence of knowledge as a principal resource. Society has become better educated and more demanding, making interested parties increasingly more powerful. This clause provides a way of thinking about the organisation more broadly, by providing fundamental concepts and principles to be used in the development of a Quality Management System.

2.2 Fundamental concepts

2.2.1 Quality

Quality focused organizations embrace a culture that inspires and drives behaviour, attitude, actions and processes in order to deliver value through fulfilling the requirements of interested parties.

The quality of an organization's products and services is determined by not only the ability to satisfy a particular customer but also the intended and unintended impact on other interested parties.

The quality of products and services include not only their intended function, but also their perceived value and benefit to the customer.

2.2.2 Quality management system

Quality management systems manage the interacting processes, sub-systems, procedures, and resources required to:

- provide value to all relevant interested parties, and
- realize the outputs, outcomes, or results of the whole organization

Anticipating the impact of outcomes is essential in managing performance.

Quality management systems provide a means of managing the cost of quality. Awareness of these costs enables organizations to take action in order to optimise utilization of resources.

2.2.3 Interested parties

Organizations learn from relevant interested parties to develop their purpose and thereby define what outputs, outcomes, or results they need to deliver to those interested parties and to society in general.

Organizations attract, capture and retain the support of organizations and individuals they depend upon for their success.

2.2.4 Context of an organization

An adaptable, open and agile organization understands its context through examination of internal and external issues impacting its purpose and sustainability. In addition to financial performance, organizations may take environmental and social responsibility into account. An organization's purpose is expressed through statements such as an organization's Vision and mission, policies, and improvement objectives.

2.2.5 Management Support

Active engagement and management support for the quality management system enables:

- the provision of adequate human and other resources,
- monitoring processes and outcomes,
- identifying risks and opportunities, and
- taking appropriate and robust actions.

Responsible acquisition, deployment, maintenance and disposal of resources satisfy the organization's objectives.

People are one of the most important resources of the organization. The performance of the organization is dependent upon how people behave within the system in which they work. A quality management system is more effective when management and individuals understand and develop the competence needed to perform their roles and responsibilities.

2.2.5.1 Awareness

People within an organization should be aligned through a common understanding of the organization's desired outcomes and how they are driven by the quality policy. Awareness is evident when individuals understand how their role contributes to the achievement of an organization's objectives.

2.2.5.2 Communication

Effective communication throughout the organization and relevant interested parties enhances involvement through better understanding of:

- the management system and its performance, and
- organizational values, objectives and strategies.

2.3 Quality management principles

2.3.1 General

The following seven quality management principles are derived from the fundamental concepts described in Sub-clause 2.1 as principles of action.

144 2.3.2 Customer focus

145 2.3.2.1 Statement

146 The primary focus of quality management is to meet customer requirements and to strive to exceed customer
147 expectations.

148 2.3.2.2 Rationale

149 Sustained success is achieved when an organization attracts and retains the confidence of customers and
150 other interested parties. Every aspect of customer interaction provides an opportunity to create more value for
151 the customer. Understanding current and future needs of customers and other interested parties contributes to
152 sustained success of the organization.

153 2.3.2.3 Key benefits

154 Some key benefits are:

- 155 • Increased customer value;
 - 156 • Increased customer satisfaction;
 - 157 • Improved customer loyalty;
 - 158 • Enhanced repeat business;
 - 159 • Enhanced reputation of the organization;
 - 160 • Expanded customer base;
 - 161 • Increased revenue and market share.
- 162

163 2.3.2.4 Actions you can take

164 Some actions you can take are:

- 165 • Recognize direct and indirect customers as those who receive value from the organization.
 - 166 • Understand customers' current and future needs and expectations.
 - 167 • Link the organization's objectives to customer needs and expectations.
 - 168 • Communicate customer needs and expectations throughout the organization.
 - 169 • Plan, design, develop, produce, deliver and support goods and services to meet customer needs and
170 expectations.
 - 171 • Measure and monitor customer satisfaction and take appropriate actions.
 - 172 • Determine and take actions on interested parties' needs and expectations that can affect customer
173 satisfaction.
 - 174 • Actively manage relationships with customers to achieve sustained success.
- 175

176 2.3.3 Leadership

177 2.3.3.1 Statement

178 Leaders at all levels establish unity of purpose and direction and create conditions in which people are
179 engaged in achieving the organization's quality objectives.

180 2.3.3.2 Rationale

181 Creation of unity of purpose and direction and engagement of people enable an organization to align its
182 strategies, policies, processes and resources to achieve its objectives.

183 2.3.3.3 Key benefits

184 Some key benefits are:

- 185 • Increased effectiveness and efficiency in meeting the organization's quality objectives;
- 186 • Better coordination of the organization's processes;

- Improved communication between levels and functions of the organization;
- Development and improvement of the capability of the organization and its people to deliver desired results.

2.3.3.4 Actions you can take

Some actions you can take are:

- Communicate the organization's mission, vision, strategy, policies and processes throughout the organization;
- Create and sustain shared values, fairness and ethical models for behavior at all levels of the organization;
- Establish a culture of trust and integrity;
- Encourage an organization-wide commitment to quality;
- Ensure that leaders at all levels are positive examples to people in the organization;
- Provide people with the required resources, training and authority to act with accountability;
- Inspire, encourage and recognize people's contribution.

2.3.4 Engagement of people

2.3.4.1 Statement

Competent, empowered and engaged people at all levels throughout the organization are essential to enhance the organization's capability to create and deliver value.

2.3.4.2 Rationale

To manage an organization effectively and efficiently, it is important to involve all people at all levels and to respect them as individuals. Recognition, empowerment and enhancement of competence facilitate the engagement of people in achieving the organization's quality objectives.

2.3.4.3 Key benefits

Some key benefits are:

- Improved understanding of the organization's quality objectives by people in the organization and increased motivation to achieve them;
- Enhanced involvement of people in improvement activities;
- Enhanced personal development, initiatives and creativity;
- Enhanced people satisfaction;
- Enhanced trust and collaboration throughout the organization;
- Increased attention to shared values and culture throughout the organization.

2.3.4.4 Actions you can take

Some actions you can take are:

- Communicate with people to promote understanding of the importance of their individual contribution;
- Promote collaboration throughout the organization;
- Facilitate open discussion and sharing of knowledge and experience;
- Empower people to determine constraints to performance and to take initiatives without fear;
- Recognize and acknowledge people's contribution, learning and improvement;
- Enable self-evaluation of performance against personal objectives;
- Conduct surveys to assess people's satisfaction, communicate the results, and take appropriate actions.

229 2.3.5 Process approach

230 2.3.5.1 Statement

231 Consistent and predictable results are achieved more effectively and efficiently when activities are understood
232 and managed as interrelated processes that function as a coherent system.

233 2.3.5.2 Rationale

234 The quality management system consists of interrelated processes. Understanding how results are produced
235 by this system enables an organization to optimize the system and its performance.

236 2.3.5.3 Key benefits

237 Some key benefits are:

- 238 • Enhanced ability to focus effort on key processes and opportunities for improvement;
- 239 • Consistent and predictable outcomes through a system of aligned processes;
- 240 • Optimized performance through effective process management, efficient use of resources, and reduced
241 cross-functional barriers;
- 242 • Enabling the organization to provide confidence to interested parties as to its consistency, effectiveness and
243 efficiency.

245 2.3.5.4 Actions you can take

246 Some actions you can take are:

- 247 • Define objectives of the system and processes necessary to achieve them;
- 248 • Establish authority, responsibility and accountability for managing processes;
- 249 • Understand the organization's capabilities and determine resource constraints prior to action;
- 250 • Determine process interdependencies and analyze the effect of modifications to individual processes on the
251 system as a whole;
- 252 • Manage processes and their interrelations as a system to achieve the organization's quality objectives
253 effectively and efficiently;
- 254 • Ensure the necessary information is available to operate and improve the processes and to monitor,
255 analyze and evaluate the performance of the overall system;
- 256 • Manage risks which can affect outputs of the processes and overall outcomes of the quality management
257 system.

259 2.3.6 Improvement

260 2.3.6.1 Statement

261 Successful organizations have an ongoing focus on improvement.

262 2.3.6.2 Rationale

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

265 2.3.6.3 Key benefits

266 Some key benefits are:

- 267 • Improved process performance, the organization's capabilities and customer satisfaction;
- 268 • Enhanced focus on root cause investigation and determination, followed by prevention and corrective
269 actions;
- 270 • Enhanced ability to anticipate and react to internal and external risks and opportunities;
- 271 • Enhanced consideration of both incremental and breakthrough improvement;

- Improved use of learning for improvement;
- Enhanced drive for innovation.

2.3.6.4 Actions you can take

Some actions you can take are:

- Promote establishment of improvement objectives at all levels of the organization;
- Educate and train people at all levels on how to apply basic tools and methodologies to achieve improvement objectives;
- Ensure people are competent to successfully promote and complete improvement projects;
- Develop and deploy processes to implement improvement projects throughout the organization;
- Track, review and audit the planning, implementation, completion and results of improvement projects;
- Integrate improvement consideration into development of new or modified goods and services and processes;
- Recognize and acknowledge improvement.

2.3.7 Evidence-based decision making

2.3.7.1 Statement

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

2.3.7.2 Rationale

Decision-making can be a complex process, and it 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.

2.3.7.3 Key benefits

Some key benefits are:

- Improved decision making processes;
- Improved assessment of process performance and ability to achieve objectives;
- Improved operational effectiveness and efficiency;
- Increased ability to review, challenge and change opinions and decisions;
- Increased ability to demonstrate the effectiveness of past decisions.

2.3.7.4 Actions you can take

Some actions you can take are:

- Determine, measure and monitor key indicators to demonstrate the organization's performance;
- Make all data needed available to the relevant people;
- Ensure that data and information are sufficiently accurate, reliable and secure;
- Analyze and evaluate data and information using suitable methods;
- Ensure people are competent to analyze and evaluate data as needed;
- Make decisions and take actions based on evidence, balanced with experience and intuition.

313 2.3.8 Relationship management

314 2.3.8.1 Statement

315 For sustained success, organizations manage their relationships with interested parties, such as suppliers.

316 2.3.8.2 Rationale

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

321 2.3.8.3 Key benefits

322 Some key benefits are:

- 323 • Enhanced performance of the organization and its interested parties through responding to the opportunities
324 and constraints related to each interested party;
- 325 • Common understanding of goals and values among interested parties;
- 326 • Increased capability to create value for interested parties by sharing resources and competence and
327 managing quality related risks;
- 328 • A well-managed supply chain that provides a stable flow of goods and services.

330 2.3.8.4 Actions you can take

331 Some actions you can take are:

- 332 • Determine relevant interested parties (such as suppliers, partners, customers, investors, employees, and
333 society as a whole) and their relationship with the organization;
- 334 • Determine and prioritize interested party relationships that need to be managed;
- 335 • Establish relationships that balance short-term gains with long-term considerations;
- 336 • Pool and share information, expertise and resources with relevant interested parties;
- 337 • Measure performance and provide performance feedback to interested parties, as appropriate, to enhance
338 improvement initiatives;
- 339 • Establish collaborative development and improvement activities with suppliers, partners and other
340 interested parties;
- 341 • Encourage and recognize improvements and achievements by suppliers and partners.

343 2.4 Development of fundamentals into a QMS

344 2.4.1 QMS model

345 Organisations share the characteristics of humans as a living and learning social organism.

346 2.4.1.1 System

347 Humans use their senses to identify, engage with, understand, and adapt to their environment in order to
348 conduct their every-day activities and achieve fulfilment. Organisations also seek to understand their
349 environment and identify those whose needs and expectations that must be satisfied to achieve the
350 organisation's objective of sustained success. Although appearing the same and often comprising similar
351 sub-systems and processes, every organisation, like every human being, is unique.

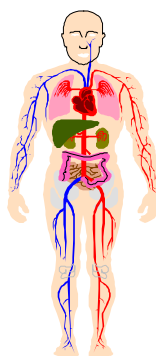


Figure 1 – The human being as a system

2.4.1.2 Process

Human beings comprise sub-systems and processes, such as the respiratory and digestive systems. Although each sub-system can be individually identified, defined, measured and improved, it is the way in which they work together that sustains life.

The organisation also has sub-systems and processes that can be identified individually, measured and improved. Consistent with human beings, it is the way in which those sub-systems and processes interact that determines the outcomes necessary to achieve sustained success. Some sub-systems and processes may be critical while others may not. This is analogous to a vital organ, in that without its proper functioning the organism will die.

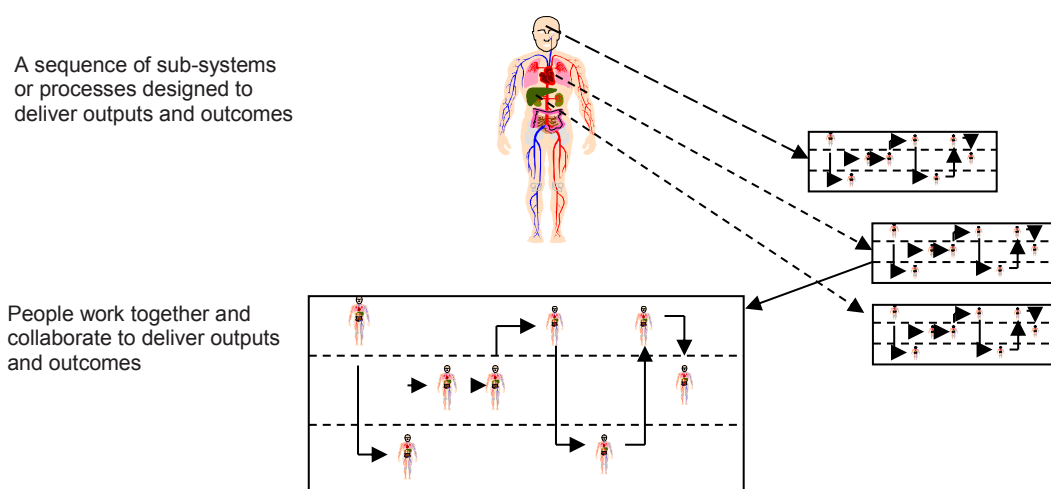


Figure 2 – System and process interface

2.4.1.3 Activity

The same people who collaborate to create and operate a process carry out their day to day activities within these processes. Some of those activities are pre-defined while others just happen as a result of an individual's understanding of the vision, values and objectives of the organisation, or reaction to external stimuli.

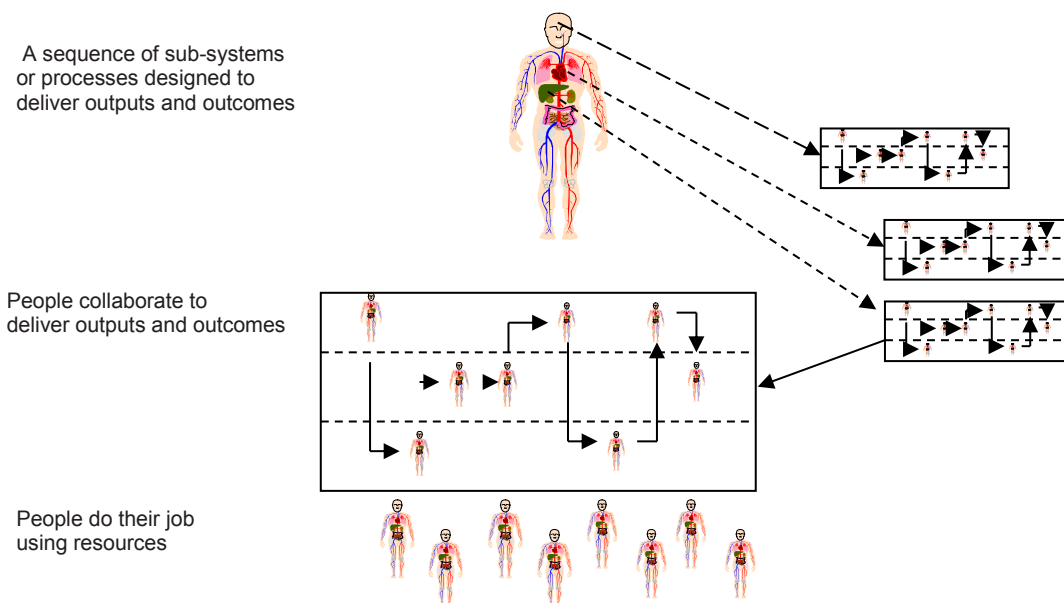


Figure 3 – The anatomy of quality management system

Human beings as a species have adapted to their environment to survive. Sometimes improvements may not be enough: organizations may use disruptive innovations to achieve the dramatic changes required to be successful.

2.4.2 Development of QMS

A Quality Management System is a dynamic living system that evolves over time through periods of improvement and innovation. Every organization has quality management activities, whether they have been formally planned or not. This document provides guidance on how to develop a formal system to manage these activities. It is not necessary to dismiss activities which already exist in the organization, ISO 9000 and ISO 9001 can be used to provide a structure that helps the organization to develop a cohesive quality management system.

A formal Quality Management System provides a framework for planning, executing, monitoring and improving the performance of quality management activities. The Quality Management System doesn't need to be complicated; rather it should accurately reflect the needs of the organization. In developing the Quality Management System, the fundamental concepts and principles given in this document can provide valuable guidance.

Planning for a Quality Management System is critical for organizations to achieve their objectives. Planning is not a singular event, rather it is an ongoing process. Plans evolve as the organization learns and circumstances change. A plan should take into account all quality activities of the organization and ensure that it covers all guidance of ISO 9000 and requirements of ISO 9001. The plan is implemented upon approval.

It is important for an organization to regularly monitor and evaluate both the implementation of the plan and the performance of the Quality Management System. Carefully considered indicators facilitate these monitoring and evaluation activities. Actions should be taken for correction and improvement based on analysis of the evidence gathered. The knowledge gained may lead to innovation, taking Quality Management System performance to higher levels.

Organizations need to have full knowledge of the causal relations between planning activities and control measures. There are many methods and models in literature to describe the development of a quality management system. One common methodology, known as PDCA, may be used to illustrate the planning,

executing, monitoring and improvement activities. It is important to plan (P), execute according to the plan (D), monitor the results (C) and improve the plan as necessary (A).

PDCA may be used during three levels of performance:

- 1) Maintenance: Take action to maintain performance at current levels, meeting objectives.
- 2) Improvement: Take action to raise performance to a higher level, meeting or exceeding objectives.
- 3) Innovation: Take action to fundamentally transform performance, by generating and utilizing new knowledge.

It is important to address the three levels with proper balance to effectively and efficiently achieve an organization's purpose and objectives. Addressing only maintenance may not realize the potential ability of the organization's processes. Likewise, attention to improvement and innovation without steady maintenance may not retain the desired results. An ideal status can be achieved by addressing all three levels.

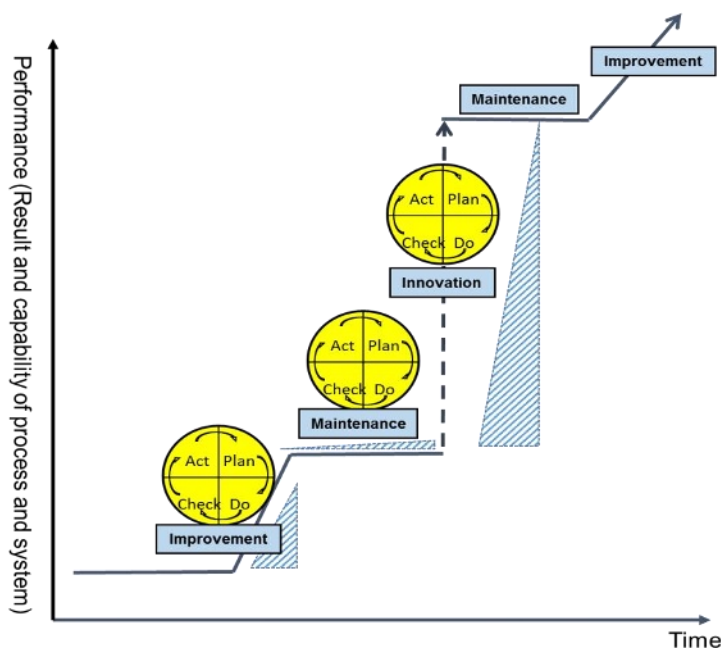


Figure 4 - QMS: three levels of performance

2.4.3 Relationship to other standards

The 21st century organisation is more complex than its predecessors and more difficult to manage, principally because it must function in an environment that few could have contemplated a few years ago. Organisations are currently not able to achieve success by standing alone.

In the past, many issues such as innovation, ethics, trust and reputation could be regarded as individual parameters excluded from day-to-day management. Success in today's organisational environment requires that these issues be given constant attention and considered as interrelated. This standard recognises and is a response to this new management context by providing common guidance for standards such as ISO 9001:2015, ISO 14001, ISO 50001 and ISO 26000.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

A term referred to in a definition or note which is defined elsewhere in this clause is indicated by italic font followed by its entry number in parentheses in regular font. These terms shall be replaceable by their definition without major change to the sense of the definition or the sentence in which it appears (10).

For example:

document (3.8.4) is defined as “*information* (3.8.1.1) and the medium on which it is contained”;

information (3.8.1.1) is defined as “meaningful *data* (3.8.1)”.

If the term “information” (3.8.1.1) is replaced by its definition, as follows:

document (3.8.4) then becomes “meaningful data and the medium on which it is contained”.

A concept limited to a special meaning in a particular context is indicated by designating the subject field in angle brackets, <>, before the definition.

EXAMPLE In the context of an *audit* (3.10.1), the term entry for technical expert is:

3.2.3

technical expert

<*audit*> (3.10.1) person who provides specific *knowledge* (3.8.3) or expertise to the *audit team* (3.10.5)

This vocabulary contains terms from all the quality management systems standards developed and published by ISO/TC 176 current at the time of the publication of this standard. The terms and definitions are arranged in conceptual order according to ISO/IEC directives and have an alphabetical list at the end of the document to aid location of entries.

3.1 Terms related to person or people

3.1.1

top management

person or group of people who directs and controls an *organization* (3.2.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the *organization* (3.2.1).

Note 2 to entry: If the scope of the *management system* (3.4.3) covers only part of an *organization* (3.2.1) then top management refers to those who direct and control that part of the *organization* (3.2.1).

3.1.2

involvement

engagement in, and contribution to, shared *objectives* (3.7.1)

[ISO 10018: 2012]

3.1.3

people involvement

involvement (2.1.2) of people through the provision of responsibility and authority to achieve desired results