NEBOSH GC 2

Study notes

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Contents

Quality management systems - Requirements

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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is Technical Committee ISO/TC 176, Quality management and quality assurance, Subcommittee SC2, Quality systems.

This 5th edition of ISO 9001 cancels and replaces the 4th edition (ISO 9001:2008). This new edition represents a technical revision compared to the earlier edition, through the adoption of a revised clause sequence, the adaptation of the revised "quality management principles" and of new concepts.

NOTE TO THIS TEXT (which will not be included in the published International Standard):

This text has been prepared using the "high-level structure" (i.e. clause sequence, common text and terminology) provided in Annex SL, Appendix 2 of the ISO/IEC Directives, Part 1, Consolidated ISO Supplement, 2013. This is intended to enhance alignment among ISO's management system standards, and to facilitate their implementation for organizations that need to meet the requirements of two or more such standards simultaneously.

The clause sequence of ISO 9001:2008 has been changed to be consistent with "Annex SL". The text of Annex SL is highlighted in the main body of the text (clauses 1 to 10) by the use of blue font. This is only to facilitate analysis and will not be incorporated in the final version of ISO 9001.

This new harmonized approach allows for the addition of discipline-specific (in this case quality-specific) text which has been applied by including the following:

A. specific quality management system requirements considered essential to meet the scope of the ISO 9001 standard;
B. text to reflect the use of the Quality Management Principles that form the basis for ISO's quality management system standards;
C. requirements and notes to clarify and ensure consistent interpretation and implementation of the common text in the context of a quality management system.

Introduction

1.1 General

The adoption of a quality management system ought to be a strategic decision for an organization. A robust quality management system can help an organization to improve its overall performance and forms an integral component of sustainable development initiatives. The design and implementation of an organization's quality management system is influenced by the context of the organisation and the changes in that context, particularly with respect to:

a) its specific objectives;
b) the risks associated with its context and objectives;
c) the needs and expectations of its customers and other relevant interested parties;
d) the products and services it provides;

e) the complexity of processes it employs and their interactions;
f) the competence of persons within or working on behalf of the organization;
g) its size and organizational structure.

The context of an organization can include internal factors such as organizational culture, and external factors such as the socio-economic conditions under which it operates; consequently all the requirements of this International Standard are generic but the ways in which they are applied can differ from one organization to another. Accordingly, it is not the intent of this International Standard to imply the need for uniformity in the structure of different quality management systems, or uniformity of documentation to align to the clause structure of this International Standard, or to impose specific terminology to be used within the organization.

The quality management system requirements specified in this International Standard are complementary to requirements for products and services.

Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, to assess the organization's ability to consistently meet customer, statutory and regulatory requirements applicable to the products and services it provides, the organization's own requirements and its aim to enhance customer satisfaction.

1.2 The ISO standards for quality management

This International Standard is one of the three core standards in the ISO portfolio of quality management system standards.

- ISO 9000 Quality management systems — Fundamentals and vocabulary provides an essential background for the proper understanding and implementation of this International Standard. The quality management principles described in detail in ISO 9000 were developed by ISO/TC 176, and have been taken into consideration during the development of this International Standard. These principles are not requirements in themselves, but they form the foundation of the requirements specified by this International Standard. An outline of the quality management principles is included in an Annex B to this International Standard.
- ISO 9001 (this International Standard) specifies requirements aimed primarily at giving confidence in the products and services provided by an organization and thereby improving customer satisfaction (see clause 1 Scope). Its proper implementation can also be expected to bring other organizational benefits such as improved internal communication, better understanding and control of the

organization's processes, and reduction in defects and waste.

- ISO 9004 Managing for the sustained success of an organization - A quality management approach provides guidance for organizations that choose to progress beyond the requirements of this International Standard to address a broader range of topics that can lead to continual improvement of the organization's overall performance. ISO 9004 includes guidance on a self-assessment methodology for an organization to be able to evaluate the level of maturity of its quality management system.

Other standards that have been developed to support the implementation of a quality management system include those in the ISO 10000 number range. These include guidelines on customer satisfaction, quality plans, quality management in projects, configuration management, measurement processes and measuring equipment, documentation, financial and economic benefits of quality management, training, statistical techniques, the involvement and competence of people, selection of quality management system consultants and auditing of management systems. These standards are described further in Annex C of this International Standard.

1.3 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. This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Clause 4.4 of this International Standard includes specific requirements considered essential to the adoption of a process approach.

The process approach applies systematic definition and management of processes and their interactions so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using a "Plan-Do- Check-Act" (PDCA) methodology (see 0.4) with an overall focus on "Risk-based thinking" aimed at preventing undesirable outcomes (see 0.5).

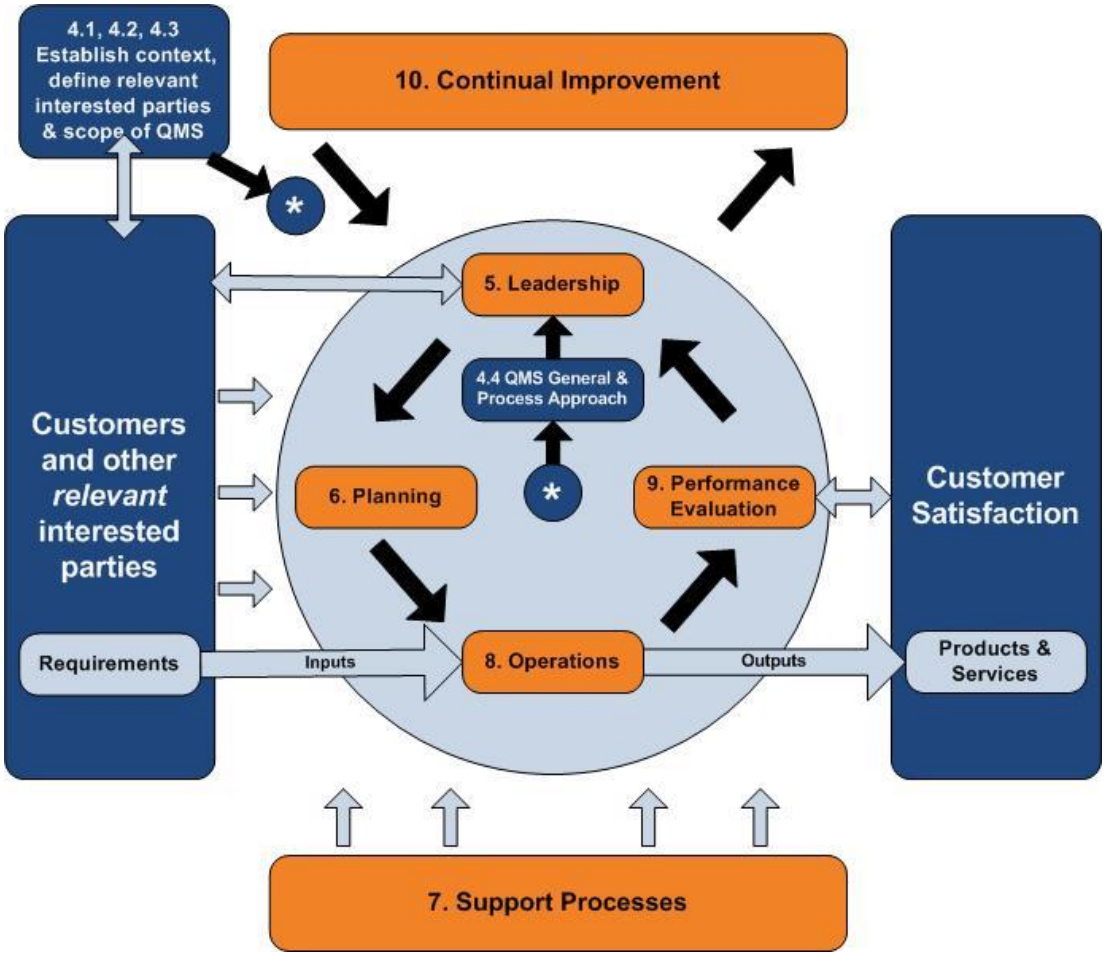
When used within a quality management system, the process approach ensures:

A. understanding and consistently meeting requirements;
B. consideration of processes in terms of added value;
C. the achievement of effective process performance;
D. improvement of processes based on evaluation of data and information.

Figure 1 illustrates the process linkages between clauses 4 to 10 of this International Standard. This shows that customers play a significant role in defining the input requirements that the organization needs to meet at all stages of its quality management system. In addition, the needs and expectations of other relevant interested parties can also play a role in defining those requirements. Monitoring of customer satisfaction requires the evaluation of information relating to customer perceptions as to whether the organization has met these requirements.

The schematic model shown in Figure 1 covers all the requirements of this International Standard, but does not show the individual processes at a detailed level. Each of these processes, and the system as a whole, can be managed using the PDCA methodology described in clause 0.4 of this International Standard.

Figure 1 - Model of a process-based quality management system, showing the links to the clauses of this International Standard



1.4 Plan-Do-Check-Act cycle

The methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes and to the quality management system as a whole. The clauses of this

International Standard broadly follow the PDCA cycle which can be briefly described as follows:

Plan: establish the objectives of the system and its component processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies.

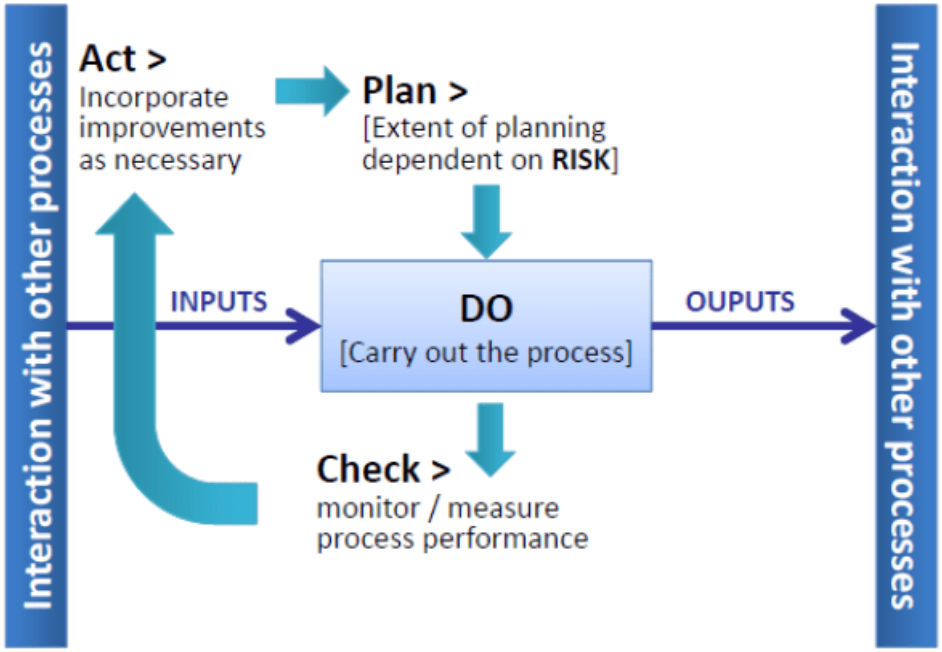
Do: implement what was planned.

Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives and requirements, and report the results.

Act: take actions to improve process performance, as necessary.

Figure 2 shows schematically how a single process within the quality management system can be managed using the PDCA cycle.

Figure 2 - Schematic representation of a single process within the system



1.5 "Risk Based Thinking"

Risk is the effect of uncertainty on an expected result and the concept of risk-based thinking has always been implicit in ISO 9001. This International Standard makes risk-based thinking more explicit and incorporates it in requirements for the establishment, implementation, maintenance and continual improvement of the quality management system. Organizations can choose to develop a more extensive risk-based approach

than is required by this International Standard, and ISO 31000 provides guidelines on formal risk management which can be appropriate in certain organizational contexts.

Not all the processes of the quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the consequences of process, product, service or system nonconformities are not the same for all organizations. For some organizations, the consequences of delivering nonconforming products and services can result in minor inconvenience to the customer; for others, the consequences can be far-reaching and fatal. "Risk-based thinking" therefore means considering risk qualitatively (and, depending on the organization's context, quantitatively) when defining the rigour and degree of formality needed to plan and control the quality management system, as well as its component processes and activities.

1.6 Compatibility with other management system standards

This International Standard has adopted the "high-level structure" (i.e. clause sequence, common text and common terminology) developed by ISO to improve alignment among its International Standards for management systems. An explanation of some of the key elements of the "high level structure" and some of the key changes introduced in this International Standard is provided in Annex A.

This International Standard defines the requirements in an order that is consistent with organizational planning and process management, i.e.:

- Understanding the context of the organization, its quality management system and processes (Clause 4)
- Leadership, policy and responsibilities (Clause 5)
- Processes for planning and consideration of risks and opportunities (Clause 6)
- Processes for support, including resources, people and information (Clause 7)
- Operational processes related to customers and products and services (Clause 8)
- Processes for performance evaluation (Clause 9)
- Processes for improvement (Clause 10).

It is important to emphasize, however, that organizations are not required to follow an identical clause-by- clause sequence when defining their quality management system, and they are encouraged to use the Process Approach as described in clauses 0.3 to 0.5 of this International Standard.

This International Standard does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or financial management. However, this International

Standard enables an organization to use the process approach, coupled with the PDCA methodology and risk-based thinking to align or integrate its quality management system with the requirements of other management system standards as it sees fit. It is possible for an organization to adapt its existing management system in order to address the requirements of this International Standard.

A matrix showing the correlation between the clauses of this International Standard and ISO 9001:2008 can be found on the ISO/TC 176/SC2 open access web site at: www.iso.org/tc176/sc02/public.

[Note to this DIS: The matrix will only be available after the June meeting of ISO/TC 176/SC2/WG23]

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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.

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ISO 9001 was prepared by Technical Committee ISO/TC 176, Quality management and Quality Assurance, Subcommittee SC 2, Quality Systems.

This second/third/... edition cancels and replaces the first/second/... edition (), [clause(s) / subclause(s) / table(s) / figure(s) / annex(es)] of which [has / have] been technically revised.