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Title: Draft BS EN ISO 9001 Quality Management Systems - Requirements

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard
i) has any issues related to 3rd party IPR, patent or copyright
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THIS DRAFT IS NOT CURRENT BEYOND 31 August 2014

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

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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.

UK Vote

Please indicate whether you consider the UK should submit a negative (with reasons) or positive vote on this draft.

Submission of Comments

- The guidance given below is intended to ensure that all comments receive efficient and appropriate attention by the responsible BSI committee. **Annotated drafts are not acceptable and will be rejected.**

- All comments must be submitted, preferably electronically, to the Responsible Committee Secretary at the address given on the front cover. Comments should be compatible with version 6.0 or version 97 of Microsoft Word for Windows, if possible; otherwise comments in ASCII text format are acceptable. **Any comments not submitted electronically should still adhere to these format requirements.**

- All comments submitted should be presented as given in the example below. Further information on submitting comments and how to obtain a blank electronic version of a comment form are available from the BSI website at: **http://drafts.bsigroup.com/**

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: **ISO/DIS xxxx**

1	2	(3)	4	5	(6)	(7)
MB	**Clause No./ Subclause No./Annex** (e.g. 3.1)	**Paragraph/ Figure/ Table/Note**	**Type of com-ment**	**Commend (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 9001

ISO/TC **176**/SC **2** Secretariat: **BSI**

Voting begins on: **2014-07-10**

Voting terminates on: **2014-10-10**

Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

ICS: 03.120.10

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.

Reference number
ISO/DIS 9001:2014(E)

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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 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

0.1 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.

0.2 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.

0.3 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.

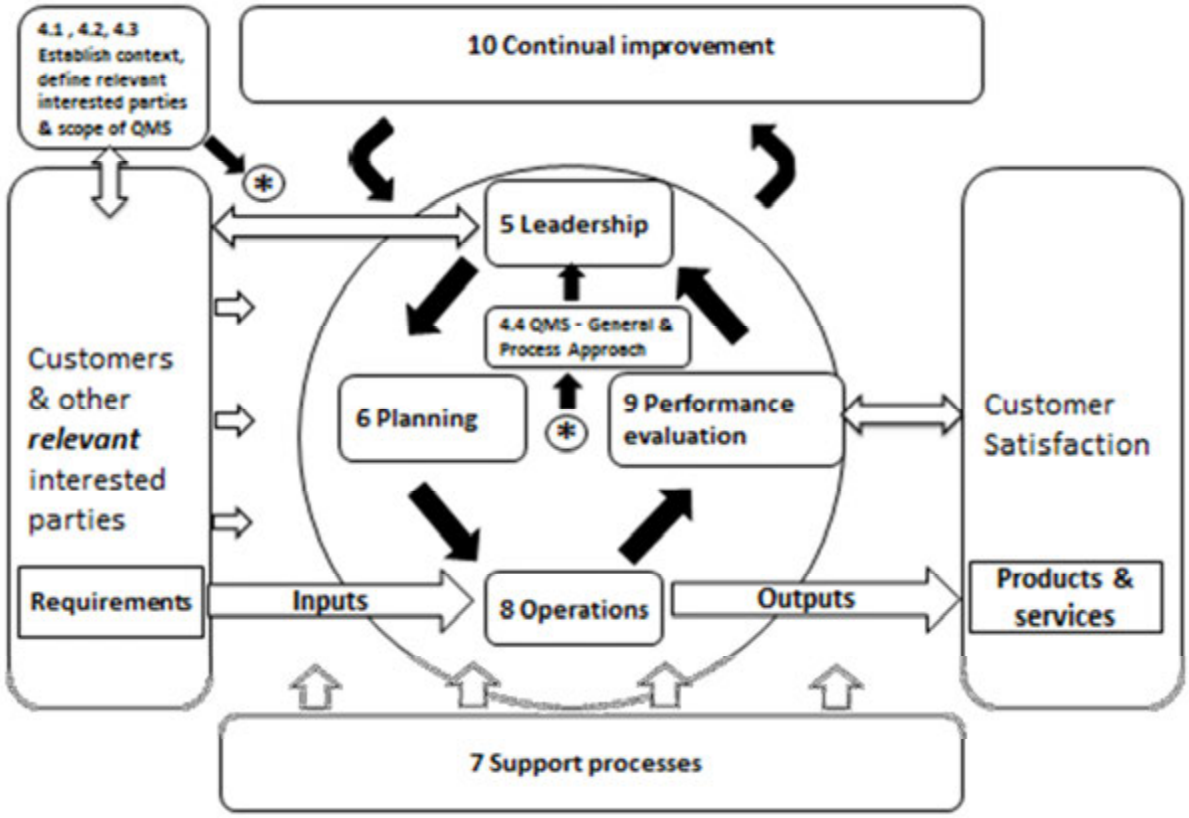


Figure 1 - Model of a process-based quality management system, showing the links to the clauses of this International Standard

0.4 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:

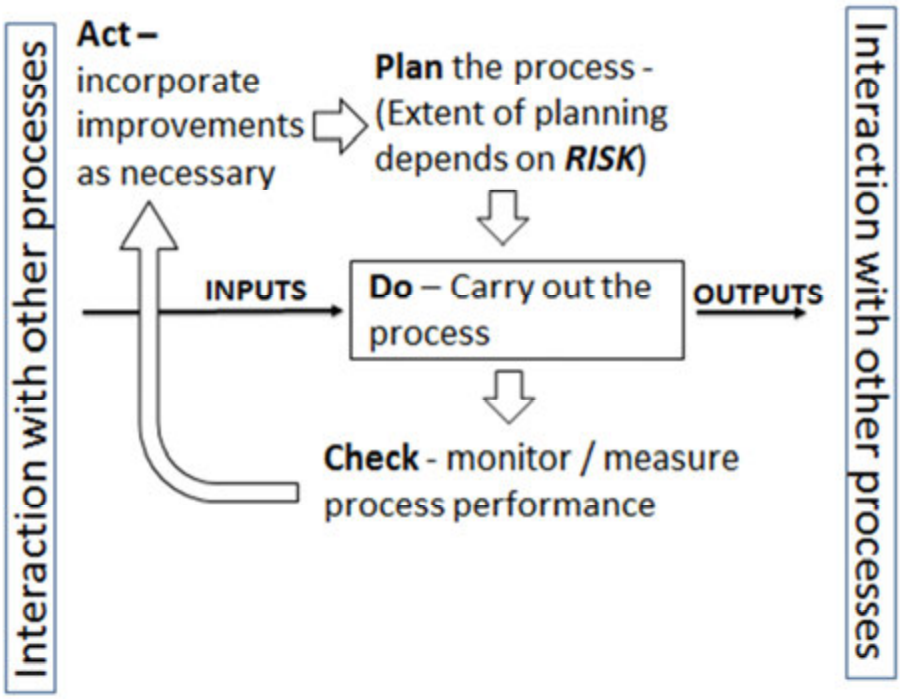
— **Plan**: establish the objectives of the system and its component processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies.

— **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.



296

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

298

299 **0.5 "Risk-based thinking"**

300 Risk is the effect of uncertainty on an expected result and the concept of risk-based thinking has
301 always been implicit in ISO 9001. This International Standard makes risk-based thinking more explicit
302 and incorporates it in requirements for the establishment, implementation, maintenance and continual
303 improvement of the quality management system. Organizations can choose to develop a more
304 extensive risk-based approach than is required by this International Standard, and ISO 31000
305 provides guidelines on formal risk management which can be appropriate in certain organizational
306 contexts.
307
308 Not all the processes of the quality management system represent the same level of risk in terms of
309 the organization's ability to meet its objectives, and the consequences of process, product, service or
310 system nonconformities are not the same for all organizations. For some organizations, the
311 consequences of delivering nonconforming products and services can result in minor inconvenience to
312 the customer; for others, the consequences can be far-reaching and fatal. "Risk-based thinking"
313 therefore means considering risk qualitatively (and, depending on the organization's context,
314 quantitatively) when defining the rigour and degree of formality needed to plan and control the quality
315 management system, as well as its component processes and activities.
316

317 **0.6 Compatibility with other management system standards**

318 This International Standard has adopted the "high-level structure" (i.e. clause sequence, common text
319 and common terminology) developed by ISO to improve alignment among its International Standards
320 for management systems. An explanation of some of the key elements of the "high level structure" and
321 some of the key changes introduced in this International Standard is provided in Annex A.
322
323 This International Standard defines the requirements in an order that is consistent with organizational
324 planning and process management, i.e.:
325

— 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]

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 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.

Quality management systems — Requirements

1 Scope

This International Standard specifies requirements for a quality management system where an organization:

a) needs to demonstrate its ability to consistently provide product or service that meets customer and applicable statutory and regulatory requirements, and