

Comparison of ISO 9001:2008 and ISO 9001:2000

This document aims to compare ISO 9001:2008 and ISO 9001:2000 to highlight changes.

The ISO 9001:2008 has been approved and the proposed standard is available at The American Society for Quality at www.asq.org ISO 9001:2008 does not introduce any additional requirements beyond the current ISO 9001:2000.

Although certification is not compulsory, it is estimated that over one million ISO 9001 certificates have been issued to organizations in private and public sectors, in manufacturing and services, and in 170 countries. The new edition, however, will not require any specific reassessment for certification.

ISO 9001:2008 will be the fourth edition of the standard which was first published in 1987. The third edition, published in 2000, represented a thorough revision, including new requirements and a sharpened customer focus, reflecting developments in quality management and experience gained since the publication of the initial version.

Compared to the current 2000 edition, ISO 9001:2008 represents fine-tuning. It introduces clarifications to the requirements in ISO 9001:2000, based on user experience over the last eight years, and changes that are intended to improve further compatibility with the ISO 14001:2004 environmental standard.

To accompany the publication of this new edition, ISO is working on implementation guidance for ISO 9001:2008, a reference table comparing and contrasting ISO 9001:2000 and ISO 9001:2008, and answers to Frequently Asked Questions


Summary of key changes between ISO 9001:2008 and ISO 9001:2000

The changes considered to provide useful clarifications are summarized in the table

Clause	Key Changes
1 Scope	Explicit to state that for the QMS the term “product” is not solely related to the product intended for the customer but also to <u>products for use in the product realization process</u> , including <u>purchased</u> products and products from <u>intermediate stages</u> in the realization process.
4.1 General requirements	Amended text to clarify how outsourced processes should be considered and controlled within the QMS.
6. Work Environment	Amended text which details factors relevant related to work environment.
7.2.1 Determination of requirements related to the product	Amended text with examples on relevant post-delivery activities.
7.3.3 Design and development outputs	Amended text states that info on preservation of product also should be considered
8.2.1 Customer satisfaction	Amended text provides examples on relevant input for monitoring of customer perception.

COMPARISON – CLAUSE BY CLAUSE

<u>ISO 9001:2008</u>	Changes/Interpretation
<p>1. Scope</p> <p>1.1 General</p> <p>This International Standard specifies requirements for a quality management system where an organization</p> <p>a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and</p> <p>b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.</p> <p>NOTE 1 In this International Standard, the term “product” applies only to the product intended for, or required by, a customer or the product realization processes. This also includes purchased product and product resulting from intermediate stages of the realization process.</p> <p>NOTE 2 Statutory and regulatory requirements may be expressed as legal requirements</p>	<p>Key Changes:</p> <p>Explicit to state that for the QMS the term “product” is not solely related to the product intended for the customer but also to <u>products for use in the product realization process</u>, including <u>purchased</u> products and products from <u>intermediate stages</u> in the realization process.</p> <p>Interpretation:</p> <p>No changes in interpretation deemed to be needed but auditors should be aware of this change.</p>
<p>1.1 Application</p> <p>All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.</p> <p>Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.</p> <p>Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organizations ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.</p>	<p>Key changes:</p> <p>Only minor editorial change.</p> <p>Interpretation:</p> <p>No changes.</p>
<p>2. Normative reference</p> <p>The following referenced normative documents are indispensable for the application of this document. contains</p>	<p>Key changes:</p> <p>Clarifies that for undated references</p>

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<p>provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, only the edition cited applies subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document (including any amendments) applies. Members of ISO and IEC maintain registers of currently valid International Standards.</p> <p>ISO 9000:2000 2005 <i>Quality management systems — Fundamentals and vocabulary.</i></p>	<p>the latest edition applies.</p> <p>Interpretation: Auditors should be aware of this.</p>
<p>3. Terms and definitions</p> <p>For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.</p> <p>The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:</p> <p style="text-align: center;">  </p> <p>The term "organization" replaces the term "supplier" used in ISO 9001 :1994, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".</p> <p>Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".</p>	<p>Key changes: Removed text relevant related to ISO 9001:1994.</p> <p>Interpretation: No changes</p>
<p>4. Quality management system</p>	
<p>4.1 General requirements</p> <p>The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.</p> <p>The organization shall</p> <ol style="list-style-type: none"> a) Identify determine the processes needed for the quality management system and their application throughout the organization (see 1.2), b) determine the sequence and interaction of these processes, c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective, 	<p>Key changes: Text amended intended to clarify how outsourced processes should be considered and controlled within the QMS</p> <p>Interpretation: No changes in interpretation deemed needed, but auditors should be aware of these amendments.</p>

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<p>d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,</p> <p>e) monitor, measure (where applicable), and analyse these processes, and</p> <p>f) implement actions necessary to achieve planned results and continual improvement of these processes.</p> <p>These processes shall be managed by the organization in accordance with the requirements of this International Standard.</p> <p>Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these Controls of such outsourced processes shall be defined within the quality management system.</p> <p>NOTE 1 Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement, analysis and improvement.</p> <p>NOTE 2 An outsourced process is identified as one being needed for the organization's quality management system but chosen to be performed by a party external to the organization.</p> <p>NOTE 3 The type and nature of control to be applied to the outsourced process may be influenced by factors such as:</p> <p>a) the potential impact of the outsourced process on the organizations capability to provide product that conforms to requirements;</p> <p>b) the extent to which the control for the process is shared;</p> <p>c) the capability of achieving the necessary control through the application of clause 7.4.</p> <p>Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements.</p>	
<p>4.2 Documentation requirements</p> <p>4.2.1 General</p>	<p>Key changes:</p> <p>Editorial changes and adds no new</p>

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<p>The quality management system documentation shall include</p> <ul style="list-style-type: none"> a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures and records required by this International Standard, and d) documents, including records, needed-determined by the organization to be necessary to ensure the effective planning, operation and control of its processes, and e) records required by this International Standard (see 4.2.4). <p>NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.</p> <p>NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to</p> <ul style="list-style-type: none"> a) the size of organization and type of activities, b) the complexity of processes and their interactions, and c) the competence of personnel. <p>NOTE 3 The documentation can be in any form or type of medium.</p>	<p>substance.</p> <p>Interpretation: No changes in interpretation.</p>
<p>4.2.2 Quality manual</p> <p>The organization shall establish and maintain a quality manual that includes</p> <ul style="list-style-type: none"> a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2), b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system. 	<p>Key changes: No changes</p>

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<p>4.2.3 Control of documents</p> <p>Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.</p> <p>A documented procedure shall be established to define the controls needed</p> <ul style="list-style-type: none"> a) to approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents, c) to ensure that changes and the current revision status of documents are identified, d) to ensure that relevant versions of applicable documents are available at points of use, e) to ensure that documents remain legible and readily identifiable, f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose. 	<p>Key changes:</p> <p>Editorial changes and adds no new substance.</p> <p>Interpretation:</p> <p>No changes in interpretation.</p>
<p>4.2.4 Control of records</p> <p>Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.</p> <p>The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.</p> <p>Records shall be remain legible, readily identifiable and retrievable.</p>	<p>Key changes:</p> <p>Editorial changes and adds no new substance.</p> <p>Interpretation:</p> <p>No changes in interpretation.</p>

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5. Management responsibility	
<p>5.1 Management commitment Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by</p> <ul style="list-style-type: none"> a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources. 	<p>Key changes: No changes</p>
<p>5.2 Customer focus Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).</p>	<p>Key changes: No changes</p>
<p>5.3 Quality policy Top management shall ensure that the quality policy</p> <ul style="list-style-type: none"> a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and 	<p>Key changes: No changes</p>

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e) is reviewed for continuing suitability.	
5. 4 Planning	
5.4.1 Quality objectives Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	Key changes: No changes
5.4.2 Quality management system planning Top management shall ensure that <ul style="list-style-type: none"> a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. 	Key changes: No changes
5.5 Responsibility, authority and communication	
5.5.1 Responsibility and authority Top management shall ensure that responsibilities and authorities are defined and communicated within the organization	Key changes: No changes
5.5.2 Management representative Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes.	Key changes: Minor editorial change and adds no new substance.

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<p>a) ensuring that processes needed for the quality management system are established, implemented and maintained,</p> <p>b) reporting to top management on the performance of the quality management system and any need for improvement, and</p> <p>c) ensuring the promotion of awareness of customer requirements throughout the organization.</p> <p>NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.</p>	<p>Interpretation: No changes in interpretation.</p>
<p>5.5.3 Internal communication</p> <p>Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.</p>	<p>Key changes: No changes</p>
<p>5.6 Management review</p>	
<p>5.6.1 General</p> <p>Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.</p> <p>Records from management reviews shall be maintained (see 4.2.4).</p>	<p>Key changes: No changes</p>
<p>5.6.2 Review input</p> <p>The input to management review shall include information on</p> <p>a) results of audits,</p> <p>b) customer feedback,</p>	<p>Key changes: No changes</p>

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<ul style="list-style-type: none"> c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement. 	
<p>5.6.3 Review output The output from the management review shall include any decisions and actions related to</p> <ul style="list-style-type: none"> a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs. 	<p>Key changes: No changes</p>
<p>6 Resource Management</p>	
<p>6.1 Provision of resources The organization shall determine and provide the resources needed</p> <ul style="list-style-type: none"> a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements. 	<p>Key changes: No changes</p>
<p>6.2 Human resources</p>	
<p>6.2.1 General Personnel performing work affecting <u>product quality conformity to product requirements</u> shall be competent on the</p>	<p>Key changes: Amended text but adds no new</p>

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<p>basis of appropriate education, training, skills and experience.</p> <p>NOTE Conformity to product requirements may be affected directly or indirectly by personnel performing any task within the quality management system.</p>	<p>substance.</p> <p>Interpretation: No changes in interpretation.</p>
<p>6.2.2 Competence, training and awareness</p> <p>The organization shall</p> <p>a) determine the necessary competence for personnel performing work affecting product quality conformity to product requirements,</p> <p>b) where applicable, provide training or take other actions to satisfy these needs achieve the necessary competence,</p> <p>c) ensure the effectiveness of the actions taken, ensure that the necessary competence has been achieved,</p> <p>d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and</p> <p>e) maintain appropriate records of education, training, skills and experience (see 4.2.4).</p>	<p>Key changes: Amended text but adds no new substance.</p> <p>Interpretation: No changes in interpretation.</p>
<p>6.3 Infrastructure</p> <p>The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable</p> <p>a) buildings, workspace and associated utilities,</p> <p>b) process equipment (both hardware and software), and</p> <p>c) supporting services (such as transport, or communication or information systems).</p>	<p>Key changes: Amended text but adds no new substance.</p> <p>Interpretation: No changes in interpretation.</p>
<p>6.4 Work environment</p> <p>The organization shall determine and manage the work environment needed to achieve conformity to product</p>	<p>Key changes: Amended text details factors relevant</p>

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<p>requirements.</p> <p>Note: The term “work environment” relates to conditions under which work is performed included physical, environmental and other factors (such as noise, temperature, humidity, lighting, or weather).</p>	<p>related to work environment.</p> <p>Interpretation: These details have most likely already been understood and covered by our auditors and does not imply any changes in interpretation.</p>
7. Product realization	
<p>7.1 Planning of product realization</p> <p>The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).</p> <p>In planning product realization, the organization shall determine the following, as appropriate:</p> <ul style="list-style-type: none"> a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4). <p>The output of this planning shall be in a form suitable for the organization’s method of operations.</p> <p>NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.</p> <p>NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.</p>	<p>Key changes: Amended text but adds no new substance.</p> <p>Interpretation: No changes in interpretation.</p>

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<p>7.2 Customer-related processes</p> <p>7.2.1 Determination of requirements related to the product</p> <p>The organization shall determine</p> <ul style="list-style-type: none"> a) requirements specified by the customer, including the requirements for delivery, and for post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related applicable to the product, and d) any additional requirements considered necessary determined by the organization. <p>NOTE Post delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.</p>	<p>Key changes:</p> <p>Amended text with examples on relevant post-delivery activities.</p> <p>Interpretation:</p> <p>Auditors should be aware of these examples, but does not imply any changes in interpretation</p>
<p>7.2.2 Review of requirements related to the product</p> <p>The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that</p> <ul style="list-style-type: none"> a) product requirements are defined, b) contract or order requirements differing from those previously expressed are resolved, and c) the organization has the ability to meet the defined requirements. <p>Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4)</p> <p>Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.</p> <p>Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.</p> <p>NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.</p>	<p>Key changes:</p> <p>No changes</p>

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<p>7.2.3 Customer communication</p> <p>The organization shall determine and implement effective arrangements for communicating with customers in relation to</p> <ul style="list-style-type: none"> a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints. 	<p>Key changes:</p> <p>No changes</p>
<p>7.3 Design and development</p> <p>7.3.1 Design and development planning</p> <p>The organization shall plan and control the design and development of product.</p> <p>During the design and development planning, the organization shall determine</p> <ul style="list-style-type: none"> a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. <p>The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibilities.</p> <p>Planning output shall be updated, as appropriate, as the design and development progresses.</p> <p>NOTE Design and development review, verification and validation have distinct purposes. They may be conducted and recorded separately or in any combination as suitable for the product and the organization.</p>	<p>Key changes:</p> <p>Amended text but adds no new substance.</p> <p>Interpretation:</p> <p>No changes in interpretation</p>
<p>7.3.2 Design and development inputs</p> <p>Inputs relating to product requirements shall be determined and records maintained (See 4.2.4). These inputs shall include</p> <ul style="list-style-type: none"> a) functional and performance requirements, b) applicable statutory and regulatory requirements, 	<p>Key changes:</p> <p>Amended text but adds no new substance.</p> <p>Interpretation:</p> <p>No changes in interpretation</p>

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<p>c) where applicable, information derived from previous similar designs, and</p> <p>d) other requirements essential for design and development.</p> <p>These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.</p>	
<p>7.3.3 Design and development outputs</p> <p>The outputs of the design and development shall be provided in a form that enables suitable for verification against the design and development input and shall be approved prior to release.</p> <p>Design and development outputs shall</p> <p>a) meet the input requirements for design and development,</p> <p>b) provide appropriate information for purchasing, production and for service provision,</p> <p>c) contain or reference product acceptance criteria, and</p> <p>d) specify the characteristics of the product that are essential for its safe and proper use.</p> <p>NOTE Information for production and service provision may include details for the preservation of product.</p>	<p>Key changes:</p> <p>Amended text states that info on preservation of product also should be considered.</p> <p>Interpretation:</p> <p>Auditors should be aware of this amendment.</p>
<p>7.3.4 Design and development review</p> <p>At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)</p> <p>a) to evaluate the ability of the results of design and development to meet requirements, and</p> <p>b) to identify any problems and propose necessary actions.</p> <p>Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (4.2.4)</p>	<p>Key changes:</p> <p>No changes</p>

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<p>7.3.5 Design and development verification</p> <p>Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (4.2.4).</p>	<p>Key changes: No changes</p>
<p>7.3.6 Design and development validation</p> <p>Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (4.2.4).</p>	<p>Key changes: No changes</p>
<p>7.3.7 Control of design and development changes</p> <p>Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.</p> <p>Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4)</p>	<p>Key changes: No changes</p>
<p>7.4 Purchasing</p> <p>7.4.1 Purchasing process</p> <p>The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.</p> <p>The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained. (see 4.2.4)</p>	<p>Key changes: No changes</p>
<p>7.4.2 Purchasing information</p> <p>Purchasing information shall describe the product to be purchased, including where appropriate</p>	<p>Key changes:</p>

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<p>c) requirements for approval of product, procedures, processes and equipment,</p> <p>d) requirements for qualification of personnel, and</p> <p>e) quality management system requirements.</p> <p>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p>	No changes
<p>7.4.3 Verification of purchased product</p> <p>The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.</p> <p>Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.</p>	<p>Key changes:</p> <p>No changes</p>
<p>7.5 Production and Service Provision</p> <p>7.5.1 Control of production and service provision</p> <p>The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable</p> <p>a) the availability of information that describes the characteristics of the product,</p> <p>b) the availability of work instructions, as necessary,</p> <p>c) the use of suitable equipment,</p> <p>d) the availability and use of monitoring and measuring equipment devices,</p> <p>e) the implementation of monitoring and measurement, and</p> <p>f) the implementation of product release, delivery and post-delivery activities.</p>	<p>Key changes:</p> <p>Amended text but adds no new substance.</p> <p>Interpretation:</p> <p>No changes in interpretation</p>

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<p>7.5.2 Validation of processes for production and service provision</p> <p>The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence, This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.</p> <p>Validation shall demonstrate the ability of these processes to achieve planned results.</p> <p>The organization shall establish arrangements for these processes including, as applicable</p> <ul style="list-style-type: none"> a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4) and e) revalidation. 	<p>Key changes:</p> <p>Amended text but adds no new substance.</p> <p>Interpretation:</p> <p>No changes in interpretation</p>
<p>7.5.3 Identification and traceability</p> <p>Where appropriate, the organization shall identify the product by suitable means throughout product realization.</p> <p>The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.</p> <p>Where traceability is a requirement, the organization shall control and record the unique identification of the product and maintain records (see 4.2.4)</p> <p>NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.</p>	<p>Key changes:</p> <p>Amended text but adds no new substance.</p> <p>Interpretation:</p> <p>No changes in interpretation</p>
<p>7.5.4 Customer property</p> <p>The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use</p>	<p>Key changes:</p> <p>Amended text but adds no new</p>

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<p>or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained the organization shall report this to the customer and maintain records (see 4.2.4).</p> <p>NOTE Customer property can include intellectual property and personal data.</p>	<p>substance.</p> <p>Interpretation: No changes in interpretation</p>
<p>7.5.5 Preservation of product</p> <p>The organization shall preserve the conformity of product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. This As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.</p>	<p>Key changes: Amended text but adds no new substance.</p> <p>Interpretation: No changes in interpretation</p>
<p>7.6 Control of monitoring and measuring devices</p> <p>The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment devices needed to provide evidence of conformity of product to determined requirements (see 7.2.4).</p> <p>The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.</p> <p>Where necessary to ensure valid results, measuring equipment shall</p> <ol style="list-style-type: none"> be calibrated and/or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4); be adjusted or re-adjusted as necessary; be identified have identification in order to determine its to enable the calibration status to be determined; be safeguarded from adjustments that would invalidate the measurement result; be protected from damage and deterioration during handling, maintenance and storage. <p>In addition, the organization shall assess and record the validity of the previous measuring results when the</p>	<p>Key changes: Amended text but adds no new substance.</p> <p>Interpretation: No changes in interpretation</p>

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<p>equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).</p> <p>When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.</p> <p>NOTE — See ISO 10012 for ISO 10012-2 for guidance.</p> <p>NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.</p>	
<p>8. Measurement, analysis and improvement</p> <p>8.1 General</p> <p>The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed</p> <p>a) to demonstrate conformity to of the product requirements,</p> <p>b) to ensure conformity of the quality management system, and</p> <p>c) to continually improve the effectiveness of the quality management system.</p> <p>This shall include determination of applicable methods, including statistical techniques, and the extent of their use.</p>	<p>Key changes: Amended text but adds no new substance.</p> <p>Interpretation: No changes in interpretation</p>
<p>8.2 Monitoring and measurement</p> <p>8.2.1 Customer satisfaction</p> <p>As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.</p> <p>NOTE Monitoring customer perception may include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.</p>	<p>Key changes: Amended text provides examples on relevant input for monitoring of customer perception.</p> <p>Interpretation: Auditors should be aware of this amendment and examples, but is not</p>

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	likely to imply changes in the interpretation.
<p>8.2.2 Internal audit</p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system</p> <p>a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and</p> <p>b) is effectively implemented and maintained.</p> <p>A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.</p> <p>An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.</p> <p>The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.</p> <p>Records of the audit and their results shall be maintained (see 4.2.4).</p> <p>The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).</p> <p>NOTE See ISO 19011, ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.</p>	<p>Key changes:</p> <p>Amended text but adds no new substance.</p> <p>Interpretation:</p> <p>No changes in interpretation</p>
<p>8.2.3 Monitoring and measurement of processes</p> <p>The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.</p> <p>NOTE When determining suitable methods, the organization should consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product</p>	<p>Key changes:</p> <p>Amended text but adds no new substance.</p> <p>Interpretation:</p>

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<p>requirements and on the effectiveness of the quality management system.</p>	<p>No changes in interpretation</p>
<p>8.2.4 Monitoring and measurement of product</p> <p>The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.</p> <p>Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).</p> <p>The release of product release and service delivery to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.</p>	<p>Key changes:</p> <p>Amended text but adds no new substance.</p> <p>Interpretation:</p> <p>No changes in interpretation</p>
<p>8.3 Control of nonconforming product</p> <p>The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product. shall be defined in a documented procedure.</p> <p>Where practicable, the organization shall deal with nonconforming product by one or more of the following ways:</p> <ol style="list-style-type: none"> by taking action to eliminate the detected nonconformity; by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; by taking action to preclude its original intended use or application. by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started, <p>Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).</p>	<p>Key changes:</p> <p>Amended text but adds no new substance.</p> <p>Interpretation:</p> <p>No changes in interpretation</p>

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<p>When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.</p> <p>Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).</p> <p>When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.</p>	
<p>8.4 Analysis of data</p> <p>The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.</p> <p>The analysis of data shall provide information relating to</p> <ul style="list-style-type: none"> a) customer satisfaction (see 8.2.1), b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers. 	<p>Key changes:</p> <p>No changes</p>
<p>8.5 Improvement</p> <p>8.5.1 Continual improvement</p> <p>The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.</p>	<p>Key changes:</p> <p>No changes</p>
<p>8.5.2 Corrective action</p> <p>The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.</p>	<p>Key changes:</p> <p>No changes</p>

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<p>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none"> a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for actions to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken. 	
<p>8.5.3 Preventive action</p> <p>The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.</p> <p>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none"> a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing preventive action taken. 	<p>Key changes:</p> <p>No changes</p>