

## ISO 9001:2000 versus ISO 9001:2008

ISO 9001:2000	ISO 9001:2008	Audit Affect
<p>4.1 General Requirements 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. The organization shall:</p> <ul style="list-style-type: none"> <li>a) identify the processes needed for the quality management system and their application through out the organization</li> <li>b) determine the sequence and interaction of these processes</li> <li>c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective</li> <li>d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes</li> <li>e) monitor measure and analyze these processes</li> <li>f) implement actions necessary to achieve planned results and continual improvement of these processes.</li> </ul> <p>These processes shall be managed by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system. NOTE Processes needed for the quality management system referred to above should include processes for management</p>	<p>4.1 General requirements 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. The organization shall</p> <ul style="list-style-type: none"> <li>a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2),</li> <li>b) determine the sequence and interaction of these processes,</li> <li>c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,</li> <li>d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,</li> <li>e) monitor, measure (where applicable), and analyse these processes, and</li> <li>f) implement actions necessary to achieve planned results and continual improvement of these processes.</li> </ul> <p>These processes shall be managed by the organization in accordance with the requirements of this International Standard. Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system. NOTE 1 Processes needed for the quality management</p>	<p>Client is now to determine the processes rather than identify them – implying that the processes do not exist on their own but are determined and established by the client – probably no affect on our audit – but we do need to increase our emphasis on the process approach – the clients processes existed and were determined before ISO 9001:2000 but they were probably not formally identified as processes and not managed as processes</p> <p>Clarifies that Control of Outsourced needs</p>

<p>activities, provision of resources, product realization and measurement.</p>	<p>system referred to above include processes for management activities, provision of resources, product realization and measurement, analysis and improvement. NOTE 2 An outsourced process is identified as one needed for the organization's quality management system but chosen to be performed by a party external to the organization. NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements, b) the degree to which the control for the process is shared, c) the capability of achieving the necessary control through the application of 7.4.</p>	<p>to be defined in the QMS processes – if auditors have not been holding clients accountable for defining these controls then we need to make sure this is audited properly</p> <p>The notes provide clarification only.</p>
<p>4.2 Documentation Requirements 4.2.1 General The quality management system documentation shall included a) documented statements of a quality policy and quality objectives b) a quality manual c) documented procedures required but this International Standard d) documents needed by the organization to ensure the effective planning, operation and control of its processes e) records required by this International Standard NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. NOTE 2 The extent of the quality management system documentation can differ from one organization to another due</p>	<p>4.2 Documentation requirements 4.2.1 General The quality management system documentation shall include 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, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes. 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 address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one</p>	<p>Minor changes to the wording to improve grammar and flow of text.</p> <p>No change for clients or auditors</p> <p>Notes allow for the intended flexibility</p>

<p>to</p> <ul style="list-style-type: none"> <li>a) the size of the organization and type of activities,</li> <li>b) the complexity of processes and their interactions, and</li> <li>c) the competence of personnel.</li> </ul> <p>NOTE 3 The documentation can be in any form or type of medium.</p>	<p>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"> <li>a) the size of the organization and type of activities,</li> <li>b) the complexity of processes and their interactions, and</li> <li>c) the competence of personnel.</li> </ul> <p>NOTE 3 The documentation can be in any form or type of medium.</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"> <li>a) the scope of the quality management system, including details of and justification for any exclusions</li> <li>b) the documented procedures established for the quality management system, or reference to them</li> <li>c) a description of the interaction between the processes of the quality management system</li> </ul>	<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"> <li>a) the scope of the quality management system, including details of, and justification for, any exclusions (see 1.2),</li> <li>b) the documented procedures established for the quality management system, or reference to them, and</li> <li>c) a description of the interaction between the processes of the quality management system.</li> </ul>	<p>No change for clients or auditors</p>
<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 <u>documented procedure</u> shall be established to define the controls needed</p> <ul style="list-style-type: none"> <li>a) to approve documents for adequacy prior to issue</li> <li>b) to review and update as necessary and re-approve documents</li> <li>c) to ensure that changes and the current revision status of documents are identified</li> <li>d) to ensure that relevant versions of applicable documents are available at points of use</li> </ul>	<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"> <li>a) to approve documents for adequacy prior to issue,</li> <li>b) to review and update as necessary and re-approve documents,</li> <li>c) to ensure that changes and the current revision status of documents are identified,</li> <li>d) to ensure that relevant versions of applicable documents are available at points of use,</li> </ul>	<p>Very minor changes to wording - No change for clients or auditors</p>

<p>e) to ensure that documents remain legible and readily identifiable</p> <p>f) to ensure that documents of external origin are identified and their distribution controlled</p> <p>g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.</p>	<p>e) to ensure that documents remain legible and readily identifiable,</p> <p>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</p> <p>g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.</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. Records shall remain legible, readily identifiable and retrievable. A <u>documented procedure</u> shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.</p>	<p>4.2.4 Control of records</p> <p>Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. 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 remain legible, readily identifiable and retrievable.</p>	<p>Very minor changes to wording – the striking of time from retention requirements does not eliminate the requirement to define retention controls which include how long records will be maintained. - No change for clients or auditors</p>
<p>5 Management responsibility</p> <p>5.1 Management Commitment</p> <p>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> <p>a) communication to the organization the importance of meeting customer as well as statutory and regulatory requirements</p> <p>b) establishing the quality policy</p> <p>c) ensuring that quality objectives are established</p>	<p>5 Management responsibility</p> <p>5.1 Management commitment</p> <p>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness by</p> <p>a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,</p> <p>b) establishing the quality policy,</p> <p>c) ensuring that quality objectives are established,</p>	<p>No change for clients or auditors</p>

<p>d) conducting management reviews e) ensuring the availability of resources</p>	<p>d) conducting management reviews, and e) ensuring the availability of resources.</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.</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>No change for clients or auditors</p>
<p>5.3 Quality Policy Top management shall ensure that the quality policy 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 e) is reviewed for continuing suitability</p>	<p>5.3 Quality policy Top management shall ensure that the quality policy 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 e) is reviewed for continuing suitability.</p>	<p>No change for clients or auditors</p>
<p>5.4 Planning 5.4.1 Quality Objectives Top management shall ensure that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.  5.4.2 Quality Management System Planning Top management shall ensure that 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 b) the integrity of the quality management system is</p>	<p>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.  5.4.2 Quality management system planning Top management shall ensure that 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</p>	<p>No change for clients or auditors</p>

<p>maintained when changes to the quality management system are planned and implemented.</p>	<p>maintained when changes to the quality management system are planned and implemented.</p>	
<p>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.</p>	<p>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.</p>	<p>No change for clients or auditors</p>
<p>5.5.2 Management Representative Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes</p> <ul style="list-style-type: none"> <li>a) ensuring that processes needed for the quality management system are established, implemented and maintained</li> <li>b) reporting to top management on the performance of the quality management system and any need for improvement</li> <li>c) ensuring the promotion of awareness of customer requirements throughout the organization</li> </ul> <p>NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.</p>	<p>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</p> <ul style="list-style-type: none"> <li>a) ensuring that processes needed for the quality management system are established, implemented and maintained,</li> <li>b) reporting to top management on the performance of the quality management system and any need for improvement, and</li> <li>c) ensuring the promotion of awareness of customer requirements throughout the organization.</li> </ul> <p>NOTE The responsibility of a management representative can include liaising with external parties on matters relating to the quality management system.</p>	<p>Clarified that the management representative is a member of the organization's management – clients that use an external consultant will need to make sure that that person is on the organization chart and has defined responsibilities and is truly engaged with the organization</p>
<p>5.5.3 Internal Communications Top management shall ensure that appropriate communication channels are established within the organization and that communication takes place regarding the effectiveness of the quality management system</p>	<p>5.5.3 Internal communication 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>No change for clients or auditors</p>
<p>5.6 Management Review 5.6.1 General</p>	<p>5.6 Management review 5.6.1 General</p>	<p>No change for clients or auditors</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. Records from management reviews shall be maintained.</p> <p>5.6.2 Review Input The input to management review shall include information on</p> <ul style="list-style-type: none"> <li>a) results of audits</li> <li>b) customer feedback</li> <li>c) process performance and product conformity</li> <li>d) status of preventive and corrective actions</li> <li>e) follow-up actions from previous management reviews</li> <li>f) changes that could affect the quality management system</li> <li>g) recommendations for improvement</li> </ul> <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"> <li>a) improvement of the effectiveness of the quality management system and its processes</li> <li>b) improvement of product related to customer requirements</li> <li>c) resource needs.</li> </ul>	<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. Records from management reviews shall be maintained (see 4.2.4).</p> <p>5.6.2 Review input The input to management review shall include information on</p> <ul style="list-style-type: none"> <li>a) results of audits,</li> <li>b) customer feedback,</li> <li>c) process performance and product conformity,</li> <li>d) status of preventive and corrective actions,</li> <li>e) follow-up actions from previous management reviews,</li> <li>f) changes that could affect the quality management system, and</li> <li>g) recommendations for improvement.</li> </ul> <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"> <li>a) improvement of the effectiveness of the quality management system and its processes,</li> <li>b) improvement of product related to customer requirements, and</li> <li>c) resource needs.</li> </ul>	
<p>6.1 Provision of Resources: The organization shall determine and provide the resources needed:</p> <ul style="list-style-type: none"> <li>a) To implement and maintain the quality management system and continually improve its effectiveness, and</li> <li>b) To enhance customer satisfaction by meeting customer requirements.</li> </ul>	<p>6 Resource management 6.1 Provision of resources The organization shall determine and provide the resources needed</p> <ul style="list-style-type: none"> <li>a) to implement and maintain the quality management system and continually improve its effectiveness, and</li> <li>b) to enhance customer satisfaction by meeting customer</li> </ul>	<p>No change for clients or auditors</p>

	requirements.	
<p>6.2 Human Resources 6.2.1 General Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.</p>	<p>6.2 Human resources 6.2.1 General Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.</p>	<p>Changed wording and added a note that indicates that competency evaluation applies to just about everyone not just people directly touching the product</p>
<p>6.2.2 Competence, Awareness and Training The organization shall a) Determine the necessary competence for personnel performing work affecting product quality, b) Provide training or take other actions to satisfy these needs, c) Evaluate the effectiveness of the actions taken, 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 e) Maintain appropriate records of education, training, skills and experience</p>	<p>6.2.2 Competence, training and awareness The organization shall a) determine the necessary competence for personnel performing work affecting conformity to product requirements, b) where applicable, provide training or take other actions to achieve the necessary competence, c) evaluate the effectiveness of the actions taken, 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 e) maintain appropriate records of education, training, skills and experience (see 4.2.4).</p>	<p>Changes to the wording that when gaps in competence are found, the organization is to train or take other actions to achieve the competence and then re-evaluate competence</p> <p>This may require some auditors to audit differently and may affect client competency-training processes; if they were just evaluating training</p>



		effectiveness and not re-evaluating competency
<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> <ul style="list-style-type: none"> <li>a) buildings, workspace and associated utilities,</li> <li>b) process equipment (both hardware and software),</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>c) supporting services (such as transport or communication).</li> </ul>	<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> <ul style="list-style-type: none"> <li>a) buildings, workspace and associated utilities,</li> <li>b) process equipment (both hardware and software), and</li> <li>c) supporting services (such as transport, communication or information systems).</li> </ul>	No change for clients or auditors
<p>6.4 Work Environment</p> <p>The organization shall determine and manage the work environment needed to achieve conformity to product requirements.</p>	<p>6.4 Work environment</p> <p>The organization shall determine and manage the work environment needed to achieve conformity to product requirements.</p> <p>NOTE The term “work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).</p>	No change for clients or auditors
<p>7 Product Realization</p> <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.</p> <ul style="list-style-type: none"> <li>a) Quality objectives and requirements for the product;</li> <li>b) the need to establish processes, documents, and provide resources specific to the product;</li> <li>c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;</li> <li>d) records needed to provide evidence that the realization</li> </ul>	<p>7 Product realization</p> <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"> <li>a) quality objectives and requirements for the product;</li> <li>b) the need to establish processes and documents, and to provide resources specific to the product;</li> <li>c) required verification, validation, monitoring, measurement,</li> </ul>	No change for clients or auditors

<p>processes and resulting product meet requirements 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>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> <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 can also apply the requirements given in 7.3 to the development of product realization processes.</p>	
<p>7.2 Customer-Related Processes 7.2.1 Determination of Requirements Related to the Product The organization shall determine</p> <ul style="list-style-type: none"> <li>a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,</li> <li>b) requirements not stated by the customer but necessary for specified or intended use, where known,</li> <li>c) statutory and regulatory requirements related to the product, and</li> <li>d) any additional requirements determined by the organization.</li> </ul> <p>7.2.2 Review of Requirements Related to the Product 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 contract or orders) and shall ensure that</p>	<p>7.2 Customer-related processes 7.2.1 Determination of requirements related to the product The organization shall determine</p> <ul style="list-style-type: none"> <li>a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,</li> <li>b) requirements not stated by the customer but necessary for specified or intended use, where known,</li> <li>c) statutory and regulatory requirements applicable to the product, and</li> <li>d) any additional requirements considered necessary by the organization.</li> </ul> <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>7.2.2 Review of requirements related to the product 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</p>	<p>No change for clients or auditors</p>

<p>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> <p>Records of the results of the review and actions arising from the review shall be maintained. Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. 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>7.2.3 Customer Communication The organization shall determine and implement effective arrangements for communicating with customers in relation to</p> <p>a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.</p>	<p>customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that</p> <p>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> <p>Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4). Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance. 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>7.2.3 Customer communication The organization shall determine and implement effective arrangements for communicating with customers in relation to</p> <p>a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints.</p>	
<p>7.3 Design and Development 7.3.1 Design and Development Planning The organization shall plan and control the design and development of product. During the design and development planning, the organization</p>	<p>7.3 Design and development 7.3.1 Design and development planning The organization shall plan and control the design and development of product. During the design and development planning, the</p>	<p>No change for clients or auditors</p>

<p>shall determine</p> <ul style="list-style-type: none"> <li>a) the design and development stages,</li> <li>b) the review, verification and validation that are appropriate to each design and development stage, and</li> <li>c) the responsibilities and authorities for design and development.</li> </ul> <p>The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.</p> <p>Planning output shall be updated, as appropriate, as the design and development progresses.</p> <p>7.3.2 Design and Development Inputs</p> <p>Inputs relating to product requirements shall be determined and records maintained. These inputs shall include</p> <ul style="list-style-type: none"> <li>a) functional and performance requirements,</li> <li>b) applicable statutory and regulatory requirements,</li> <li>c) where applicable, information derived from previous similar designs, and</li> <li>d) other requirements essential for design and development.</li> </ul> <p>These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.</p>	<p>organization shall determine</p> <ul style="list-style-type: none"> <li>a) the design and development stages,</li> <li>b) the review, verification and validation that are appropriate to each design and development stage, and</li> <li>c) the responsibilities and authorities for design and development.</li> </ul> <p>The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.</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 can be conducted and recorded separately or in any combination, as suitable for the product and the organization.</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"> <li>a) functional and performance requirements,</li> <li>b) applicable statutory and regulatory requirements,</li> <li>c) where applicable, information derived from previous similar designs, and</li> <li>d) other requirements essential for design and development.</li> </ul> <p>The 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 Developments Outputs</p> <p>The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.</p> <p>Design and development outputs shall</p>	<p>7.3.3 Design and development outputs</p> <p>The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.</p>	<p>No change for clients or auditors</p>

<p>a) meet the input requirements for design and development,  b) provide appropriate information for purchasing, production and for service provision,  c) contain or reference product acceptance criteria, and  d) specify the characteristics of the product that are essential for its safe and proper use.</p>	<p>Design and development outputs shall  a) meet the input requirements for design and development,  b) provide appropriate information for purchasing, production and service provision,  c) contain or reference product acceptance criteria, and  d) specify the characteristics of the product that are essential for its safe and proper use.  NOTE Information for production and service provision can include details for the preservation of product.</p>	
<p>7.3.4 Design and Development Review  At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements  a) to evaluate the ability of the results of design and development to meet requirements  b) to identify any problems and propose necessary actions  Participants in such reviews shall include representatives of functions concerned with the design and development state(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained.  7.3.5 Design and Development Verification  Verification shall be performed in accordance with planned arrangements 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.  7.3.6 Design and Development Validation  Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, when 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</p>	<p>7.3.4 Design and development review  At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)  a) to evaluate the ability of the results of design and development to meet requirements, and  b) to identify any problems and propose necessary actions.  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 (see 4.2.4).  7.3.5 Design and development verification  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 (see 4.2.4).  7.3.6 Design and development validation  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</p>	<p>No change for clients or auditors</p>

<p>maintained.</p>	<p>necessary actions shall be maintained (see 4.2.4).</p>	
<p>7.3.7 Control of Design and Development Changes 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. Records of the results of the review of changes and any necessary actions shall be maintained</p>	<p>7.3.7 Control of design and development changes 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. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).</p>	<p>No change for clients or auditors</p>
<p>7.4 Purchasing 7.4.1 Purchasing Process 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. 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.</p>	<p>7.4 Purchasing 7.4.1 Purchasing process 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. 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>No change for clients or auditors</p>
<p>7.4.2 Purchasing Information Purchasing information shall describe the product to be purchased, including where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements.</p>	<p>7.4.2 Purchasing information Purchasing information shall describe the product to be purchased, including, where appropriate, a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements.</p>	<p>No change for clients or auditors</p>

<p>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p>	<p>The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.</p>	
<p>7.4.3 Verification of Purchased Product The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. 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>7.4.3 Verification of purchased product The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. 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>No change for clients or auditors</p>
<p>7.5 Production and Service Provision 7.5.1 Control of Production and Service Provision The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment. d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities.</p>	<p>7.5 Production and service provision 7.5.1 Control of production and service provision The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable, a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring equipment, e) the implementation of monitoring and measurement, and f) the implementation of product release, delivery and post-delivery activities.</p>	<p>No change for clients or auditors</p>
<p>7.5.2 Validation of Processes for Production and Service Provision The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been</p>	<p>7.5.2 Validation of processes for production and service provision 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, deficiencies become apparent only after the product is in use or the service has been delivered.</p>	<p>No change for clients or auditors</p>

<p>delivered. Validation shall demonstrate the ability of these processes to achieve planned results, The organization shall establish arrangements for these processes including, as applicable</p> <ul style="list-style-type: none"> <li>a) defined criteria for review and approval of the processes,</li> <li>b) approval of equipment and qualification of personnel,</li> <li>c) use of specific methods and procedures,</li> <li>d) requirements for records, and</li> <li>e) revalidation</li> </ul>	<p>Validation shall demonstrate the ability of these processes to achieve planned results. The organization shall establish arrangements for these processes including, as applicable,</p> <ul style="list-style-type: none"> <li>a) defined criteria for review and approval of the processes,</li> <li>b) approval of equipment and qualification of personnel,</li> <li>c) use of specific methods and procedures,</li> <li>d) requirements for records (see 4.2.4), and</li> <li>e) revalidation.</li> </ul>	
<p>7.5.3 Identification and Traceability Where appropriate, the organization shall identify the product by suitable means throughout product realization, The organization shall identify the product status with respect to monitoring and measurement requirements, Where trace ability is a requirement, the organization shall control and record the unique identification of the product, Note: In some industry sectors, configuration management is a means by which identification and trace ability are maintained.</p>	<p>7.5.3 Identification and traceability Where appropriate, the organization shall identify the product by suitable means throughout product realization. The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization. Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4). NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.</p>	<p>No change for clients or auditor - minor changes to wording to improve clarity</p>
<p>7.5.4 Customer Property 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 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. Note: Customer property can include intellectual property.</p>	<p>7.5.4 Customer property 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 or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4). NOTE Customer property can include intellectual property and personal data.</p>	<p>No change for clients or auditor - minor changes to wording</p>



<p>7.5.5 Preservation of Product The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.</p>	<p>7.5.5 Preservation of product The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.</p>	<p>No change for clients or auditor - minor changes to wording</p>
<p>7.6 Control of Monitoring and Measuring Devices The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements 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. Where necessary to ensure valid results, measuring equipment shall  <ul style="list-style-type: none"> <li>a) be calibrated or verified 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;</li> <li>b) be adjusted or re-adjusted as necessary;</li> <li>c) be identified to enable the calibration status to be determined;</li> <li>d) be safeguarded from adjustments that would invalidate the measurement result;</li> <li>e) be protected from damage and deterioration during handling, maintenance and storage,</li> </ul>           In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any</p>	<p>7.6 Control of monitoring and measuring equipment The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. 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. Where necessary to ensure valid results, measuring equipment shall  <ul style="list-style-type: none"> <li>a) be calibrated 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);</li> <li>b) be adjusted or re-adjusted as necessary;</li> <li>c) have identification in order to determine its calibration status;</li> <li>d) be safeguarded from adjustments that would invalidate the measurement result;</li> <li>e) be protected from damage and deterioration during handling, maintenance and storage.</li> </ul>           In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any</p>	<p>No change for clients or auditor - minor changes to wording (device to equipment)</p>

<p>product affected. Records of the results of calibration and verification shall be maintained. 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. Note: See ISO 10012-1 and ISO 10012-2 for guidance.</p>	<p>product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4). 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. 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>Note clarifies the application of the clause 7.6 requirements to software.</p>
<p>8.1 General The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use.</p>	<p>8 Measurement, analysis and improvement 8.1 General The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity to product requirements, b) to ensure conformity of the quality management system, and c) to continually improve the effectiveness of the quality management system. This shall include determination of applicable methods, including statistical techniques, and the extent of their use.</p>	<p>No change for clients or auditor</p>
<p>8.2 Monitoring and Measurement 8.2.1 Customer Satisfaction 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>8.2 Monitoring and measurement 8.2.1 Customer satisfaction 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. NOTE Monitoring customer perception can include obtaining</p>	<p>No change for clients or auditor  Note added to give</p>



<p><b>8.2.3 Monitoring and Measurement of Processes</b> 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><b>8.2.3 Monitoring and measurement of processes</b> 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. NOTE When determining suitable methods, it is advisable that the organization 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 requirements and on the effectiveness of the quality management system.</p>	<p>The word “to ensure conformity of the product” have been removed – monitoring and measurement of processes applies to all processes including non-product realization processes</p>
<p><b>8.2.4 Monitoring and Measurement of Product</b> 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. Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product. Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.</p>	<p><b>8.2.4 Monitoring and measurement of product</b> 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. Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4). The release of product and delivery of service 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>No change for clients or auditor</p>
<p><b>8.3 Control of Nonconforming Product</b> The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and</p>	<p><b>8.3 Control of nonconforming product</b> 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</p>	<p>No change for clients or auditor - minor changes to wording</p>

<p>related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.</p> <p>The organization shall deal with nonconforming product by one or more of the following ways:</p> <ul style="list-style-type: none"> <li>a) by taking action to eliminate the detected nonconformity;</li> <li>b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;</li> <li>c) by taking action to preclude its original intended use or application.</li> </ul> <p>Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.</p> <p>When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.</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>documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.</p> <p>Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:</p> <ul style="list-style-type: none"> <li>a) by taking action to eliminate the detected nonconformity;</li> <li>b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;</li> <li>c) by taking action to preclude its original intended use or application;</li> <li>d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.</li> </ul> <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>8.4 Analysis of Data</p> <p>The organization shall determine, collect and analyze 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"> <li>a) customer satisfaction</li> <li>b) conformity to product requirements</li> <li>c) characteristics and trends of processes and products including opportunities for preventive action, and</li> <li>d) suppliers.</li> </ul>	<p>8.4 Analysis of data</p> <p>The organization shall determine, collect and analyze 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"> <li>a) customer satisfaction (see 8.2.1),</li> <li>b) conformity to product requirements (see 8.2.4),</li> <li>c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and</li> </ul>	<p>No change for clients or auditor</p>

	d) suppliers (see 7.4).	
<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>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>	No change for clients or auditor
<p>8.5.2 Corrective Action</p> <p>The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.</p> <p>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none"> <li>a) reviewing nonconformities (including customer complaints),</li> <li>b) determining the causes of nonconformities,</li> <li>c) evaluating the need for action to ensure that nonconformities do not recur,</li> <li>d) determining and implementing action needed,</li> <li>e) records of the results of action taken, and</li> <li>f) reviewing corrective action taken.</li> </ul>	<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>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none"> <li>a) reviewing nonconformities (including customer complaints),</li> <li>b) determining the causes of nonconformities,</li> <li>c) evaluating the need for action to ensure that nonconformities do not recur,</li> <li>d) determining and implementing action needed,</li> <li>e) records of the results of action taken (see 4.2.4), and</li> <li>f) reviewing the effectiveness of the corrective action taken.</li> </ul>	Now explicit that corrective actions must be reviewed for effectiveness – this should not be a change – both ASR auditors and clients should have been doing this before
<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"> <li>a) determining potential nonconformities and their causes,</li> <li>b) evaluating the need for action to prevent occurrence of</li> </ul>	<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"> <li>a) determining potential nonconformities and their causes,</li> <li>b) evaluating the need for action to prevent occurrence of</li> </ul>	Now explicit that preventive actions must be reviewed for effectiveness – this should not be a change – both ASR auditors and clients should have been doing this before

<p>nonconformities, c) determining and implementing action needed, d) records of results of action taken, and e) reviewing preventive action taken.</p>	<p>nonconformities, c) determining and implementing action needed, d) records of results of action taken (see 4.2.4), and e) reviewing the effectiveness of the preventive action taken.</p>	
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