

ISO 9001-2001 QMS Standards and Requirements

ISO Sections	ISO Standards	Requirements
4	Quality management system	
4.1	General requirements	<p><i>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 Standards</i></p>
		<p><i>The Organisation shall:</i></p> <ul style="list-style-type: none"> <i>a) identify the processes needed for the quality management system and their application throughout the organisation,</i> <i>b) determine the sequence and interaction of these processes,</i> <i>c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,</i> <i>d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,</i> <i>e) monitor, measure and analyse these processes, and</i> <i>f) implement actions necessary to achieve planned results and continual improvement of these processes.</i> <p><i>These processes shall be managed by the organisation in accordance with the requirements of this International Standard.</i></p> <p><i>Where the organisation chooses to outsource any process that affects product conformity with requirements, the organisation shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system</i></p> <p>Note: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realisation and measurement.</p>

4.2	Documentation requirements	
4.2.1	General	<p><i>The quality management system documentation shall include</i></p> <ul style="list-style-type: none"> <i>a) documented statements of a quality policy and quality objectives,</i> <i>b) a quality manual</i> <i>c) documented procedures required by this International Standard,</i> <i>d) documents needed by the organisation to ensure effective planning, operation and control of its processes, and</i> <i>e) records required by this International Standard.</i> <i>f)</i> <p>Note 1: Where the term “ documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.</p> <p>Note 2: The extent of the quality management system documentation can differ from one organisation to another due to: -</p> <ul style="list-style-type: none"> a) the size of organisation and type of activities, b) the complexity of processes and their interactions, and c) the competence of personal. <p>Note 3: The documentation can be in any form or type of medium.</p>
4.2.2	Quality manual	<p><i>The organisation shall establish and maintain a quality manual that includes</i></p> <ul style="list-style-type: none"> <i>a) the scope of the quality management system, including details of and justification for any exclusions,</i> <i>b) the documented procedures established for the quality management system, or reference to them, and</i> <i>c) a description of the interaction between processes of the quality management system.</i>
4.2.2	Control of documents	<p><i>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.</i></p> <p><i>A documented procedure shall be established to define the controls needed</i></p> <ul style="list-style-type: none"> <i>a) to approve documents for adequacy prior to issue</i> <i>b) to review and update as necessary and re-approve documents,</i> <i>c) to ensure that changes and the current revision status of documents are identified,</i>

		<p>d) to ensure that relevant versions of applicable documents are available at points of use,</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, 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>
4.2.4	Control of records	<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 documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.</p>
5	Management responsibility	
5.1	Management commitment	<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) communicating to the organisation the importance of meeting customer as well as statutory and regulatory requirements,</p> <p>b) establishing the quality policy,</p> <p>c) ensuring the quality objectives are established,</p> <p>d) conducting management reviews and</p> <p>e) ensuring the availability of resources.</p>
5.2	Customer focus	<p>Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction,</p>
5.3	Quality policy	<p>Top management shall ensure that the quality policy:</p> <p>a) is appropriate to the purpose of the organisation</p> <p>b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,</p> <p>c) provides a framework for establishing and reviewing quality objectives,</p>

		<p>d) <i>is communicated and understood within the organisation and,</i></p> <p>e) <i>is reviewed for continuing suitability.</i></p>
5.4	Planning	
5.4.1	Quality objectives	<i>Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organisation. The quality objectives shall be measurable and consistent with the quality policy.</i>
5.4.2	Quality management system planning	<p><i>Top management shall ensure that:-</i></p> <p>a) <i>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</i></p> <p>b) <i>the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.</i></p>
5.5	Responsibility, authority and communication	
5.5.1	Responsibility and authority	<i>Top management shall ensure that responsibilities and authorities are defined and communicated within the organisation</i>

5.5.2	Management representative	<p><i>Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:-</i></p> <ul style="list-style-type: none"> <i>a) ensuring that processes needed for the quality management system are established, implemented and maintained,</i> <i>b) reporting to top management on the performance of the quality management system and any need for improvement, and</i> <i>c) ensuring the promotion of awareness of customer requirements throughout the organisation.</i> <p>Note: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system</p>
5.5.3	Internal communication	<p><i>Top management shall ensure that appropriate communication channels are established within the organisation and that communication takes place regarding the effectiveness of the quality management system.</i></p>
5.6	Management review	
5.6.1	General	<p><i>Top management shall review the organisation'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</i></p>
5.6.2	Review input	<p><i>The input to management review shall include information on:-</i></p> <ul style="list-style-type: none"> <i>a) results of audits,</i> <i>b) customer feedback,</i> <i>c) process performance and product conformity</i> <i>d) status of preventive and corrective actions,</i> <i>e) follow-up actions from previous management reviews,</i> <i>f) changes that affect the quality management system, and</i> <i>g) recommendations for improvement.</i>

5.6.3	Review output	<i>The output from the management review shall include any decisions and actions related to :- 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.</i>
6	Resource management	
6.1	Provision of resources	<i>The organisation shall determine and provide the resources needed:- a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.</i>
6.2	Human resources	
6.2.1	General	<i>Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.</i>
6.2.2	Competence, awareness and training	<i>The organisation 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.</i>
6.3	Infrastructure	<i>The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:-</i>

		<ul style="list-style-type: none"> a) buildings, workshops and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication)
6.4	Work environment	<i>The organisation shall determine and manage the work environment needed to achieve conformity to product requirements.</i>
7	Product realization	
7.1	Planning of product realisation	<p><i>The organisation shall plan and develop the processes needed for product realisation. Planning of product realisation shall be consistent with the requirements of the other processes of the quality management system</i></p> <p><i>In planning product realisation, the organisation shall determine the following, as appropriate:</i></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 project; c) required verification, valuation, monitoring inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realisation processes and resulting product meet requirements. <p><i>The output of this planning shall be in a form suitable for the organisation's method of operations.</i></p> <p>Note 1: A document specifying the processes of the quality management system (including the product realisation processes) and the resources to be applied to be specific product, projector contract, can be referred to as a quality plan</p> <p>Note 2: The organisation may also apply the requirements given in 7.3 to the development of product realisation processes.</p>

7.2	Customer related processes	
7.2.1	Determination of requirements related to the product	<p><i>The organisation shall determine:-</i></p> <ul style="list-style-type: none"> <i>a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,</i> <i>b) requirements not stated by the customer but necessary for specified or intended use, where known,</i> <i>c) Statutory and regulatory requirements related to the product, and,</i> <i>d) any additional requirements determined by the organisation</i>
7.2.2	Review of requirements related to the product	<p><i>The organisation shall review the requirements related to the product. This review shall be conducted prior to the organisation's commitment to supply a product to the customer (e.g submission of tenders, acceptance of contracts or orders, acceptance of charges to contract or orders) and shall ensure that:</i></p> <ul style="list-style-type: none"> <i>a) product requirements are defined,</i> <i>b) contractor order requirements differing from those previously expressed are resolved, and</i> <i>c) the organisation has the ability to meet the defined requirements.</i> <p><i>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 organisation before acceptance.</i></p> <p><i>Where product requirements are changed, the organisation shall ensure that relevant documents are amended and that relevant personal are made aware of the changed requirements.</i></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 advertising material.</p>
7.2.3	Customer communication	<p><i>The organisation shall determine and implement effective arrangements for communicating with customers in relation to:</i></p> <ul style="list-style-type: none"> <i>a) product information,</i> <i>b) enquiries, contracts or order handling, including amendments and</i> <i>c) customer feedback, including customer complaints</i>

7.3	Design and development	
7.3.1	Design and development planning	<p><i>The organisation shall plan and control the design and development of product.</i></p> <p><i>During the design and development planning the organisation shall determine:</i></p> <ul style="list-style-type: none"> <i>a) the design and development stages,</i> <i>b) the review, verification and valuation that are appropriate to each design and development stage, and</i> <i>c) the responsibilities and authorities for design and development.</i> <p><i>The organisation shall manage the interfaces between different group involved in design and development to ensure effective communication and clear assignment of responsibility.</i></p> <p><i>Planning output shall be updated, as appropriate, as the design and development progresses</i></p>
7.3.2	Design and development inputs	<p><i>Inputs relating to products requirements shall be determined and records maintained. These shall include:</i></p> <ul style="list-style-type: none"> <i>a) functional and performance requirements,</i> <i>b) applicable statutory and regulatory requirements,</i> <i>c) where applicable, information derived from previous similar designs and</i> <i>d) other requirements essential for design and development.</i> <p><i>These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.</i></p>
7.3.3	Design and development output	<p><i>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.</i></p> <p><i>Design and development outputs shall</i></p> <ul style="list-style-type: none"> <i>a) meet the input requirements for design and development,</i> <i>b) provide appropriate information for purchasing, production and for service provision,</i> <i>c) contain or reference acceptance criteria, and</i> <i>d) specify the characteristics of the product that are essential for its safe and proper use.</i>

.7.3.4	Design and development review	<p><i>At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements</i></p> <p><i>a) to evaluate the ability of the results of design and development to meet requirements, and</i></p> <p><i>b) to identify any problems and propose necessary actions.</i></p> <p><i>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.</i></p>
7.3.5	Design and development verification	<p><i>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</i></p>
7.3.6	Design and development validation	<p><i>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 maintained.</i></p>
7.3.7	Control of design and development changes	<p><i>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.</i></p> <p><i>Records of the results of the review of changes and any necessary actions shall be maintained</i></p>
7.4	Purchasing	
7.4.1	Purchasing process	<p><i>The organisation shall ensure that purchased product conforms to specified purchase requirements. The type and extent of applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realisation or the final product.</i></p> <p><i>The organisation shall evaluate and select suppliers based on their ability to supply product in accordance with the organisation's requirements. Criteria for selection, evaluation and re-</i></p>

		<i>evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.</i>
7.4.2	Purchasing information	<p><i>Purchasing information shall describe the product to be purchased, including where appropriate.</i></p> <ul style="list-style-type: none"> <i>a) requirements for approval of product, procedures, processes and equipment,</i> <i>b) requirements for qualification of personnel, and</i> <i>c) quality management system requirements.</i> <p><i>The organisation shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier</i></p>
7.4.3	Verification of purchased product	<p><i>The organisation shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.</i></p> <p><i>Where the organisation or its customer intends to perform verification at the supplier's premises, the organisation shall state the intended verification arrangements and method of product release in the purchasing information</i></p>
7.5	Product and service provision	
7.5.1	Control of production and service provision	<p><i>The organisation shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable</i></p> <ul style="list-style-type: none"> <i>a) the availability of information that describes the characteristics of the product</i> <i>b) the availability of work instructions, as necessary,</i> <i>c) the use of suitable equipment,</i> <i>d) the availability and use of monitoring and measuring devices,</i> <i>e) the implementation of monitoring and measurement. And</i> <i>f) the implementation of release, delivery and post-delivery activities.</i>

<p>7.5.2</p>	<p>Validation of processes for production and service provision</p>	<p><i>The organisation 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 the deficiencies become apparent only after the product is in use or the service has been delivered.</i></p> <p><i>Validation shall demonstrate the ability of these processes to achieve planned results.</i></p> <p><i>The organisation shall establish arrangements for these processes including, as applicable</i></p> <ul style="list-style-type: none"> <i>a) defined criteria for review and approval of the processes,</i> <i>b) approval of equipment and qualification of personnel,</i> <i>c) use of specific methods and procedures,</i> <i>d) requirements for records, and</i> <i>e) revalidation.</i>
<p>7.5.3</p>	<p>Identification and traceability</p>	<p><i>Where appropriate, the organisation shall identify the product by suitable means throughout product realisation.</i></p> <p><i>The organisation shall identify the product status with respect to monitoring and measurement requirements.</i></p> <p><i>Where traceability is a requirement, the organisation shall control and record the unique identification of the product.</i></p> <p>Note: In some industry sectors, configuration is a means by which identification and traceability are maintained.</p>
<p>7.5.4</p>	<p>Customer property</p>	<p><i>The organisation shall exercise care with customer property while it is under the organisation's control or being used by the organisation. The organisation 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.</i></p> <p>Note: Customer property can include intellectual property</p>
<p>7.5.5.</p>	<p>Preservation of product</p>	<p><i>The organisation 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.</i></p>

<p>7.6</p>	<p>Control of monitoring and measuring devices</p>	<p><i>The organisation 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 organisation 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.</i></p> <p><i>Where necessary to ensure valid results, measuring equipment shall:</i></p> <ul style="list-style-type: none"> <i>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;</i> <i>b) be adjusted or re-adjusted as necessary;</i> <i>c) be identified to enable calibration status to be determined;</i> <i>d) be safeguarded from adjustments that would invalidate the measurement result;</i> <i>e) be protected from damage and deterioration during handling, maintenance and storage.</i> <p><i>In addition, the organisation shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organisation shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.</i></p> <p><i>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.</i></p> <p>Note: See ISO 10012-1 and ISO 10012-2 for guidance.</p>
<p>8.</p>	<p>Measurement, analysis and improvement</p>	
<p>8.1</p>	<p>General</p>	<p><i>The organisation shall plan and implement the monitoring, measurement, analysis and improvement processes needed:</i></p> <ul style="list-style-type: none"> <i>a) to demonstrate conformity of the product,</i> <i>b) to ensure conformity of the quality management system, and</i> <i>c) to continually improve the effectiveness of the quality management system.</i> <p><i>This shall include determination of applicable methods, including statistical techniques, and the extent of their use.</i></p>

8.2	Monitoring and measurement	
8.2.1	Customer satisfaction	<i>As one of the measurements of the performance of the quality management system the organisation shall monitor information relating to customer perception as to whether the organisation has met customer requirements. The methods for obtaining and using this information shall be determined.</i>
8.2.2	Internal audit	<p><i>The organisation shall conduct internal audits at planned intervals to determine whether the quality management system:</i></p> <ul style="list-style-type: none"> <i>a) conforms to the planned arrangements, to the requirements of this International Standard and to the quality management system requirements established by the organisation, and</i> <i>b) is effectively implemented and maintained.</i> <p><i>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 processes. Auditors shall not audit their own work.</i></p> <p><i>The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in documented procedure.</i></p> <p><i>The management responsible for the area being audited shall ensure that 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.</i></p> <p><i>Note: see ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance</i></p>
8.2.3	Monitoring and measurement of processes	<i>The organisation 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.</i>
8.2.4	Monitoring and measurement of product	<i>The organisation 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 realisation process in accordance with the planned arrangements.</i>

		<p><i>Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorising release of product.</i></p> <p><i>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.</i></p>
8.3	Control of nonconforming product	<p><i>The organisation 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 related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.</i></p> <p><i>The organisation shall deal with nonconforming product by one or more of the following ways:</i></p> <ul style="list-style-type: none"> <i>a) by taking action to eliminate the detected nonconformity;</i> <i>b) by authorising its use, release or acceptance under concession by relevant authority and, where applicable, by the customer;</i> <i>c) by taking action to preclude its original intended use or application.</i> <p><i>Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.</i></p> <p><i>When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.</i></p> <p><i>When nonconforming product is detected after delivery or use has started, the organisation shall take action appropriate to the effects, or potential effects, of the nonconformity.</i></p>
8.4	Analysis of data	<p><i>The organisation 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 result of monitoring and measurement and from other relevant sources.</i></p> <p><i>The analysis of data shall provide information relating to :</i></p> <ul style="list-style-type: none"> <i>a) customer satisfaction,</i> <i>b) conformity to product requirements</i> <i>c) characteristics and trends of processes and products including opportunities for prevention action and Suppliers.</i>

8.5	Improvement	
8.5.1	Continual improvement	<i>The organisation 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.</i>
8.5.2	Corrective action	<p><i>The organisation 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.</i></p> <p><i>A documented procedure shall be established to define requirements for</i></p> <ul style="list-style-type: none"> <i>a) reviewing nonconformities (including customer complaints),</i> <i>b) determining the causes of nonconformities,</i> <i>c) evaluating the need for action to ensure that nonconformities do not recur,</i> <i>d) determining and implementing action needed,</i> <i>e) records of the results of action taken, and</i> <i>f) reviewing corrective action taken.</i>
8.5.3	Preventive action	<p><i>The organisation 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.</i></p> <p><i>A documented procedure shall be established to define requirements for</i></p> <ul style="list-style-type: none"> <i>a) determining potential nonconformities and their causes,</i> <i>b) evaluating the need for action to prevent occurrence of nonconformities,</i> <i>c) determining and implementing action needed,</i> <i>d) records of results of action taken, and</i> <i>e) reviewing preventive action taken.</i>