

2.5 Gap analysis template ISO 9001:2000



ISO 9001:2000 Requirements	Status yes/no/none	Action
4. Quality Management System		
4.1 General requirements		
Are processes in place needed for QMS and their application throughout the organisation have been determined?		
Has the sequence and interaction of these processes have been determined?		
Does the criteria and methods needed to ensure both the operation and control of these processes are effective have been determined?		
Does the availability of resources and information needed to support the operation and monitoring of these processes are ensured?		
Are these processes are monitored, measured and analysed?		
Are actions needed to achieve planned results and continual improvement of these processes is implemented?		
4.2 Documentation requirements		
4.2.2 Quality manual		
Has a quality manual been established and is it maintained?		
Does the scope of the manual include details of and justification for any exclusion?		
Does the manual contain or references the documented procedures established for the QMS?		
Does the manual contain a description of the interaction between the processes of the QMS?		
4.2.3 Control of Documents		
Are all QMS documents controlled?		
Is a documented procedure established to define the controls needed to:		
Approve documents for adequacy prior to issue?		
review and update as needed and re-approve documents?		
ensure that changes and the current revision status of documents are identified?		
ensure that relevant versions of applicable documents are available at points of use?		
ensure that documents remain legible and readily identifiable.		
ensure that documents of external origin are identified and their distribution controlled?		
prevent the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose?		
4.2.4 Control of records		
Are records legible, readily identifiable and retrievable?		
Has a documented procedure been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?		
5.1 Management commitment		
Does top management communicate the importance of meeting		

customer, statutory and regulatory requirements?		
Is a quality policy established?		
Are quality objectives established?		

5.2 Customer focus		
Has top management ensured that customer requirements are determined and are met with the aim of enhancing customer satisfaction?		

5.3 Quality policy		
Is the policy appropriate to the purpose of the organisation?		
Does the policy include a commitment to comply with requirements and continually improve the effectiveness of the QMS?		
Does the policy provide a framework for establishing and reviewing quality objectives?		
Is the policy communicated among personnel and understood?		
Is the policy reviewed for continuing suitability?		

5.4 Planning		
5.4.1 Quality objectives		
Are the quality objectives, incl. those needed to meet requirements for product, established at relevant functions and levels within the organisation?		
Are the quality objectives measurable and consistent with the quality policy?		

5.4.2 QMS planning		
Is the QMS planning carried out in order to meet the requirements given in 4.1, as well as the quality objectives?		
Is the integrity of the QMS maintained when changes to the QMS are planned and implemented?		

5.5 Responsibility, authority and communication		
5.5.1 Responsibility and authority		
Are responsibilities and authorities defined and communicated?		

5.5.2 Management representative		
Has top management assigned a Management representative who reports on the performance of the QMS and needs for improvement?		
Does the MR ensure the promotion of awareness of customer requirements throughout the organisation?		

5.5.3 Internal communication		
Is an appropriate communication processes established?		
Is communication taking place regarding the effectiveness of the QMS?		

5.6 Management review		
5.6.1 General		
Does top management reviews the QMS at planned intervals, to ensure its continuing suitability, adequacy and effectiveness?		
Does the review include assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives?		
Are the records from management reviews are maintained?		

5.6.2 Review output		
Includes results of audits?		
Includes customer feedback?		
Includes process performance and product conformity?		
Includes status of preventive and corrective actions?		
Includes follow-up actions from previous management reviews?		
Includes changes that could affect the QMS?		
Includes recommendations for improvement?		

5.6.3 Review output		
Includes improvement of the effectiveness of the QMS and its processes?		
Includes improvement of product release to customer requirements?		
Includes resources needed?		

6. Resource management		
6.1 Provision of resources		
Is the organisation determined and provided the resources needed to implement and maintain the QMS and continually improve its effectiveness?		
Is the organisation determined and provided the resources needed to enhance customer satisfaction by meeting customer requirements?		

6.2 Human resources		
6.2.1 General		
Are the personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience?		

6.2.2 Competence, awareness and training		
Are the needed competences of personnel to perform work affecting product quality determined?		
Has training been provided or other actions taken to satisfy these competency/awareness/training needs?		
Has the effectiveness of the actions taken been evaluated?		
Are the personnel aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives?		
Are records of education, training, skills and experience maintained?		

6.3 Infrastructure		
Has the organisation determined, provided and maintained the infrastructure needed to achieve conformity to product requirements? (This includes, as applicable, buildings, workspace, equipment and supporting services)		

6.4 Work environment		
Has the organisation determined and manages work environment to achieve conformity to product requirements?		

7. Product realisation		
7.1 Planning of product realisation		
Has the organisation planned and developed the processes needed for product realisation? Is planning of product realisation consistent with the requirements of the other processes of the QMS?		

Is in planning product realisation, the organisation determined to realise the following, as appropriate:		
quality objectives and requirements for the product?		
the need to establish processes, documents, and provide resources specific to the product?		
required verification, validation, monitoring, inspection and test activities specific to the product?		
records needed to provide evidence that the realisation processes and the resulting product meet requirements?		
the output of this planning is in a form suitable for the organisation's method of operation?		

7.2 Customer-related processes		
7.2.1 Determination of requirements related to the product		
Are the requirements specified by the customer, including the requirements for delivery and post-delivery activities determined?		
Are the requirements not stated by the customer but needed for specified or intended use, where known determined?		
Are the statutory and regulatory requirements related to the product determined?		
Are additional requirements determined by the organisation determined?		

7.2.2 Review of requirements related to the product		
Is the organisation reviewing the requirements related to the product?		
Is this review 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 changes to contracts or orders)		
Does the review ensures that:		
product requirements are defined?		
contract or order requirements differing from those previously expressed are resolved?		
the organisation has the ability to meet the defined requirements?		
records of the results of the review and actions arising from the review are maintained?		
Where the customer provides no documented statement of requirement, the customer requirements are confirmed by the organisation before acceptance?		
Where product requirements are changed, the organisation ensures that relevant personnel are made aware of the changed requirements?		

7.3.2. Customer communication		
Has the organisation determined and implemented effective arrangements for communicating with customers in relationship to:		
product information?		
enquiries, contracts or order handling, including amendments?		
customer feedback, including customer complaints?		

7.3 Design and development		
7.3.1 Design and development planning		
Does the organisation plans and controls the design and development of product?		
Does during the design and development planning, the organisation determines the:		
design and development stages?		

review, verification and validation that are appropriate to each design and development stage?		
Does the organisation manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility?		
Is planning output updated, as appropriate, as the design and development progresses?		

7.3.2 Design and development inputs		
Are inputs relating to product requirements determined and records maintained?		
Does product requirements include:		
functional and performance requirements?		
applicable statutory and regulatory requirements?		
where applicable, information derived from previous similar designs?		
other requirements essential for design and development?		
Are these inputs reviewed for adequacy? Requirements are complete, unambiguous and not in conflict with each other?		

7.3.3 Design and development outputs		
Are the outputs of design and development provided in a form that enables verification against the design and development input and shall be approved prior to release?		
Do design and development outputs:		
meet the input requirements for design and development?		
provide appropriate information for purchasing, production and for service provision?		
contain or reference product acceptance criteria?		
specify the characteristics of the product that are essential for its safe and proper use?		

7.3.4 Design and development review		
Are at suitable stages, systematic reviews of design and development performed in accordance with planned arrangements to:		
evaluate the ability of the results of design and development to meet requirements?		
identify any problems and propose needed actions?		
Participants in such reviews include representatives of functions concerned with the design and development stages being reviewed?		
Records of the results of the reviews and any needed actions are maintained?		

7.3.5 Design and development verification		
Is verification performed in accordance with planned arrangements to ensure that the design and development outputs met the design and development input requirements?		
Are records of the results of the verification and any needed actions maintained?		

7.3.6 Design and development validation		
Is design and development validation performed in accordance with planned arrangements so that the resulting product is capable of meeting the requirements for the specified application or intended use, where known?		

Wherever practicable, is validation completed prior to the delivery or implementation of the product?		
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7.3.7 Control of design and development changes		
Is design and development changes identified and records are maintained?		
Are the changes reviewed, verified and validated, as appropriate, and approved before implementation?		
Is the review of design and development changes included in the effect of changes on constituent parts and product already delivered?		
Are records of the results of the review of changes and any needed actions maintained?		

7.4 Purchasing		
7.4.1 Purchasing process		
Does the organisation ensure that the purchased product conforms to specified purchase requirements?		
Does the type and extent of control applied to the supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realisation or the final product?		
Does the organisation evaluate and selects suppliers based on their ability to supply product in accordance with the organisation's requirements?		
Are criteria for the selection, evaluation and re-evaluation of suppliers established?		
Are records of the results of evaluations and any needed actions arising from the evaluation maintained?		

7.4.2 Purchasing information		
Does purchasing information describe the product purchased?		
Where appropriate, does purchasing information includes: requirements for approval of product, procedures, processes and equipment?		
requirements for qualification of personnel?		
QMS requirements?		
Does the organisation ensure the adequacy of specified purchase requirements prior to their communication to the supplier?		

7.4.3 Verification of purchased product		
Has the organisation established and implemented the inspection, or other activities, needed for ensuring that purchased product meets specified purchase requirements?		
When the organisation or its customer intends to perform verification at the supplier's premises, does the organisation states the intended verification arrangements and method of product release in the purchasing information?		

7.5 Production and service provision		
7.5.1 Control of production and service provision		
Does the organisation plans and carries out production and service provision under controlled conditions?		
Does controlled conditions include, as applicable, the: availability of information that described the characteristics of the product?		
availability of work instructions, as needed?		
use of suitable equipment?		

availability and use of monitoring and measuring devices?		
implementation of monitoring and measurement?		
implementation of release, delivery and post delivery activities?		

7.5.2 Validation of processes for production and service provision		
Does the organisation validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement?		
Does validation demonstrates the ability of these processes to achieve planned results?		
Has the organisation established arrangements for these processes including, as applicable:		
defined criteria for review and approval of the processes?		
approval of equipment and qualification of personnel?		
use of specific methods and procedures?		
requirements of records?		
revalidation?		

7.5.3 Identification and traceability		
Where appropriate, has the organisation identified the product by suitable means throughout product realisation?		
Does the organisation identify the product status with respect to monitoring and measurement requirements?		
Where traceability is a requirement, does the organisation controls and records the unique identification of the product?		

7.5.4 Customer property (can include intellectual property)		
Does the organisation exercises care with customer property while it is under the organisation's control or being used by the organisation?		
Does the organisation identifies, verifies, protects and safeguards 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, is this reported to the customer and records are maintained?		

7.5.5 Preservation of product.		
Does the organisation preserves the conformity of product during internal processing and delivery to the intended destination?		
Does this preservation include identification, handling, packaging, storage and protection?		
Does preservation also applies to the constituent parts of a product?		

7.6 Control of monitoring and measuring devices.		
Does the organisation determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determine requirements?		
Has the organisation established 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 needed to ensure valid results, is measuring equipment:		
Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to measurement standards?		
Where no such standard exist, the basis used for calibration or verification is recorded?		
Adjusted or re-adjusted as necessary?		

Identified to enable the calibration status to be determined?		
Safeguarded from adjustments that would invalidate the measurement results?		
Protected from damage and deterioration during handling, maintenance and storage?		
Does the organisation assesses and records the validity of the previous measuring results when the equipment is found not to conform requirements?		
Does the organisation take appropriate action on the equipment and product affected?		
Are records of the results of calibration and verification maintained?		
When used in the monitoring and measurement of specified requirements, is the ability of computer software to satisfy the intended application confirmed. Is this undertaken prior to initial use and reconfirmed as needed?		

8 Measurement, analysis and improvement		
8.1 General		
Does the organisation plans and implements the monitoring, measurement, analysis and improvement processes needed to: demonstrate conformity of the product?		
ensure conformity of the QMS?		
continually improve the effectiveness of the QMS?		
Does this include determination of applicable methods, including statistical techniques, and the extent of their use?		

8.2 Monitoring and measurement		
8.2.1 Customer satisfaction		
As one of the measurements of performance of the QMS, does the organisation monitors information relating to customer perception as to whether the organisation has met customer requirements?		
Has the method for obtaining and using this information been determined?		

8.2.2. Internal audit		
Are internal audits conducted at planned intervals?		
Are internal audits determine whether the QMS; conforms to the planned arrangements to requirements of ISO 9001 and to the QMS requirements established by the organisation? is effectively implemented and maintained?		
Is the audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits?		
Are the audit criteria, scope, frequency and methods defined?		
Is by the selection of auditors and the conduct of audits ensured objectivity and impartiality of the audit process?		
Do auditors not audit their own work?		
Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records defined in a documented procedure?		
Is ensured that actions are taken undue delay to eliminate detected non-conformities and their causes?		
Are follow-up activities included in the verification of the actions taken and the reporting of verification results?		

8.2.3 Monitoring and measurement process		
Does the organisation apply suitable methods for monitoring and where applicable, measurement of the QMS processes?		
Are these methods demonstrating the ability of the processes to achieve planned results?		
When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product?		

8.2.4 Monitoring and measurement of product		
Does the organisation monitors and measures the characteristics of the product to verify that product requirements have been met?		
Is this carried out at appropriate stages of the product realisation process in accordance with the planned arrangements?		
Is evidence of conformity with the acceptance criteria is maintained?		
Do records indicate the person(s) authorising product release?		
Do product release and service delivery not proceed until the planned arrangements (7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer?		

8.3 Control of non-conforming product		
Does the organisation ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery?		
Are the controls and related responsibilities and authorities for dealing with non-conforming product defined in a documented procedure?		
Does the organisation deals with non-conforming product by one or more of the following ways:		
by taking action to eliminate the detected non-conformity?		
by authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer?		
by taking action to preclude its original intended use of application?		
Records of the nature of non-conformities and any subsequent actions taken, including concessions obtained are maintained?		
Where non-conforming product is corrected is it subject to re-verification to demonstrate conformity to the requirements?		
When non-conforming product is detected after delivery or use has started, does the organisation takes action appropriate to the effects, or potential effects, of the non-conformity?		

8.4 Analysis of data		
The organisation has determined, collected and analysed appropriate data to demonstrate the suitability and effectiveness of the QMS and has evaluated where continual improvement of the effectiveness of the QMS can be made.		
customer satisfaction (8.2.1)?		
conformity to product requirements (7.2.1)?		
characteristics and trends of processes and products including opportunities for preventive action?		
suppliers ?		

8.5 Improvement		
8.5.1 Continual improvement		
Does the organisation continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review?		

8.5.2 Corrective action		
Has the organisation taken action to eliminate the cause of non-conformities in order to prevent recurrence?		
Are corrective actions appropriate to the effects of the non-conformities encountered?		
Is a documented procedure established to define requirements for:		
reviewing non-conformities, including customer complaints?		
determining the causes of non-conformities?		
evaluating the need for action to ensure that non-conformities do not recur?		
determining and implementing action needed?		
records of the results of action taken?		
reviewing corrective action taken?		

8.5.3 Preventive action		
Does the organisation determine action to eliminate the causes of potential non-conformities in order to prevent their occurrence?		
Are preventive actions appropriate to the effects of the potential problems?		
Is a documented procedure established to define requirements for:		
determining potential non-conformities and their causes?		
evaluating the need for action to prevent occurrence of non-conformities?		
determining and implementing action needed?		
records of results of actions taken (4.2.4)?		
reviewing preventive action taken?		

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