



# ISO 9001:2000 Gap Analysis Checklist

**Type:**

**Assessor:**

ISO 9001 REQUIREMENTS	STATUS	ACTION/COMMENTS
<b>4 Quality Management System</b>		
<b>4.1 General Requirements</b>		
Processes needed for the quality management system and their application throughout Company X have been determined.		
The sequence and interaction of these processes have been determined.		
Criteria and methods needed to ensure that both the operation and control of these processes are effective have been determined.		
The availability of resources and information necessary to support the operation and monitoring of these processes are ensured.		
These processes are monitored, measured and analysed.		
Actions necessary to achieve planned results and continual improvement of these processes are implemented.		
<b>4.2 Documentation Requirements</b>		
<b>4.2.2 Quality Manual</b>		
A quality manual has been established and is maintained.		
The scope of the manual includes details of and justification for any exclusions (exclusions are limited to clause 7).		
The manual contains or references the documented procedures established for the quality management system.		
The manual contains a description of the interaction between the processes of the quality management system.		
<b>4.2.3 Control Of Documents</b>		
All QMS documents are controlled.		
A documented procedure is established to define the controls needed to:		
Approve documents for adequacy prior to issue.		
Review and update as necessary 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.		
<b>4.2.4 Control Of Records</b>		
Records are legible, readily identifiable and retrievable.		
A documented procedure has been established to define the controls needed for the identification, storage, protection,		

<b>5.1 Management Commitment</b>		
Top management has communicated the importance of meeting customer, statutory and regulatory requirements.		
Quality policy is established.		
Quality objectives are established.		
<b>5.2 Customer Focus</b>		
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).		
<b>5.3 Quality Policy</b>		
Policy is appropriate to the purpose of Company X.		
Policy includes a commitment to comply with requirements and continually improve the effectiveness of the QMS.		
Policy provides a framework for establishing and reviewing quality objectives.		
Policy is communicated and understood.		
Policy is reviewed for continuing suitability.		
<b>5.4 Planning</b>		
<b>5.4.1 Quality Objectives</b>		
Quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within Company X.		
The quality objectives are measurable and consistent with the quality policy.		
<b>5.4.2 Quality Management System Planning</b>		
QMS planning is carried out in order to meet the requirements given in 4.1, as well as the quality objectives.		
The integrity of the QMS is maintained when changes to the QMS are planned and implemented.		
<b>5.5 Responsibility, Authority And Communication</b>		
<b>5.5.1 Responsibility And Authority</b>		
Responsibilities and authorities are defined and communicated.		
<b>5.5.2 Management Representative</b>		
The Quality Systems Manager reports to top management on the performance of the QMS and any need for improvement.		
The Quality Systems Manager ensures the promotion of awareness of customer requirements throughout Company X.		
<b>5.5.3 Internal Communication</b>		
Appropriate communication processes are established.		
Communication takes place regarding the effectiveness of the QMS.		
<b>5.6 Management Review</b>		
<b>5.6.1 General</b>		
Top management reviews the QMS at planned intervals, to ensure its continuing suitability, adequacy & effectiveness.		
The review includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives.		
Records from management reviews are maintained.		
<b>5.6.2 Review Input</b>		
Includes results of audits.		
Includes customer feedback.		
Includes process performance and product conformity.		
Includes status of preventive and corrective actions		

reviews.		
Includes changes that could affect the QMS.		
Includes recommendations for improvement.		
<b>5.6.3 Review Output</b>		
Includes improvement of the effectiveness of the QMS and its processes.		
Includes improvement of product related to customer requirements.		
Includes resource needs.		
<b>6 Resource Management</b>		
<b>6.1 Provision Of Resources</b>		
Company X determines and provides the resources needed to implement and maintain the QMS and continually improve its effectiveness.		
Company X determines and provides the resources needed to enhance customer satisfaction by meeting customer requirements.		
<b>6.2 Human Resources</b>		
<b>6.2.1 General</b>		
Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience.		
<b>6.2.2 Competence, Awareness And Training</b>		
The necessary competence of personnel to perform work affecting product quality has been determined.		
Training has been provided or other actions taken to satisfy these competency/awareness/training needs.		
The effectiveness of the actions taken has been evaluated.		
Personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.		
Records of education, training, skills and experience are maintained.		
<b>6.3 Infrastructure</b>		
Company X has determined, provided and maintained the infrastructure needed to achieve conformity to product requirements. (This includes, as applicable, buildings, workspace, utilities, process equipment and supporting services)		
<b>6.4 Work Environment</b>		
Company X has determined and manages the work environment to achieve conformity to product requirements.		
<b>7 Product Realization</b>		
<b>7.1 Planning Of Product Realization</b>		
Company X has planned and developed the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the QMS.		
In planning product realization, the organization shall determine 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 realization processes and resulting product meet requirements.		
The output of this planning is in a form suitable for Company X's method of operations.		
<b>7.2 Customer-Related Processes</b>		
<b>7.2.1 Determination Of Requirements Related To The Product</b>		
The requirements specified by the customer, including the requirements for delivery and post-delivery activities are determined.		
The requirements not stated by the customer but necessary for specified or intended use, where known, are determined.		
The statutory and regulatory requirements related to the product are determined.		
Additional requirements determined by the organization are determined.		
<b>7.2.2 Review Of Requirements Related To The Product</b>		
Company X reviews the requirements related to the product.		
This review is conducted prior to Company X'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).		
The review ensures that:		
Product requirements are defined.		
Contract or order requirements differing from those previously expressed are resolved.		
The organization 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 Company X before acceptance.		
Where product requirements are changed, Company X ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.		
<b>7.2.3 Customer Communication</b>		
Company X has determined and implemented effective arrangements for communicating with customers in relation to:		
Product information.		
Enquiries, contracts or order handling, including amendments.		
Customer feedback, including customer complaints.		
<b>7.3 Design And Development</b>		
<b>7.3.1 Design And Development Planning</b>		
Company X plans and controls the design and development of product.		
During the design and development planning, Company X determines the:		
Design and development stages.		
Review, verification and validation that are appropriate to each design and development stage.		

Company X manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.		
Planning output is updated, as appropriate, as the design and development progresses.		
<b>7.3.2 Design And Development Inputs</b>		
Inputs relating to product requirements are determined and records maintained.		
Product requirement inputs 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.		
These inputs are reviewed for adequacy. Requirements are complete, unambiguous and not in conflict with each other.		
<b>7.3.3 Design And Development Outputs</b>		
The outputs of design and development are provided in a form that enables verification against the design and development input and shall be approved prior to release.		
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.		
<b>7.3.4 Design And Development Review</b>		
At suitable stages, systematic reviews of design and development are 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 necessary actions.		
Participants in such reviews 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 are maintained.		
<b>7.3.5 Design And Development Verification</b>		
Verification is performed in accordance with planned arrangements to ensure that the design and development outputs met the design and development input requirements.		
Records of the results of the verification and any necessary actions are maintained.		
<b>7.3.6 Design And Development Validation</b>		
Design and development validation is 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, validation is completed prior to the delivery or implementation of the product.		

<b>7.3.7 Control Of Design And Development Changes</b>		
Design and development changes are identified and records maintained.		
The changes are reviewed, verified and validated, as appropriate, and approved before implementation.		
The review of design and development changes is included in 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 are maintained.		
<b>7.4 Purchasing</b>		
<b>7.4.1 Purchasing Process</b>		
Company X ensures that purchased product conforms to specified purchase requirements.		
The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.		
Company X evaluates and selects suppliers based on their ability to supply product in accordance with Company X's requirements.		
Criteria for the selection, evaluation and re-evaluation of suppliers are established.		
Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.		
<b>7.4.2 Purchasing Information</b>		
Purchasing information describes the product to be purchased.		
Where appropriate, purchasing information includes:		
Requirements for approval of product, procedures, processes and equipment.		
Requirements for qualification of personnel.		
Quality management system requirements.		
Company X ensures the adequacy of specified purchase requirements prior to their communication to the supplier.		
<b>7.4.3 Verification Of Purchased Product</b>		
Company X has established and implemented the inspection, or other activities, necessary for ensuring that purchased product meets specified purchase requirements.		
Where Company X or its customer intends to perform verification at the supplier's premises, Company X states the intended verification arrangements and method of product release in the purchasing information.		
<b>7.5 Production And Service Provision</b>		
<b>7.5.1 Control Of Production And Service Provision</b>		
Company X plans and carries out production and service provision under controlled conditions.		
Controlled conditions include, as applicable, the:		
Availability of information that describes the characteristics of the product.		
Availability of work instructions, as necessary.		
Use of suitable equipment.		
Availability and use of monitoring and measuring devices.		
Implementation of monitoring and measurement.		
Implementation of release, delivery and post-delivery		

<b>7.5.2 Validation Of Processes For Production And Service Provision</b>		
Company X validates 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 delivered)		
Validation demonstrates the ability of these processes to achieve planned results.		
The organization has established arrangements for these processes including, as applicable:		
Defined criteria for review & approval of the processes.		
Approval of equipment & qualification of personnel.		
Use of specific methods and procedures.		
Requirements for records.		
Revalidation.		
<b>7.5.3 Identification And Traceability</b> (In some industry sectors, configuration management is a means by which identification and traceability are maintained)		
Where appropriate, Company X has identified the product by suitable means throughout product realization.		
Company X identifies the product status with respect to monitoring and measurement requirements.		
Where traceability is a requirement, Company X controls and records the unique identification of the product.		
<b>7.5.4 Customer Property</b> (can include intellectual property)		
Company X exercises care with customer property while it is under Company X's control or being used by Company X.		
Company X 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, this is reported to the customer and records maintained.		
<b>7.5.5 Preservation Of Product</b>		
Company X preserves the conformity of product during internal processing and delivery to the intended destination.		
This preservation includes identification, handling, packaging, storage and protection.		
Preservation also applies to the constituent parts of a product.		
<b>7.6 Control Of Monitoring And Measuring Devices</b>		
Company X determines the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.		
Company X has 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 necessary to ensure valid results, measuring equipment is:		
Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to		

where no such standards 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 result.		
Protected from damage and deterioration during handling, maintenance and storage.		
Company X assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements.		
Company X takes appropriate action on the equipment and any product affected.		
Records of the results of calibration and verification are maintained.		
When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.		
<b>8 Measurement, Analysis And Improvement</b>		
<b>8.1 General</b>		
Company X plans and implements the monitoring, measurement, analysis and improvement processes needed to:		
Demonstrate conformity of the product.		
Ensure conformity of the quality management system.		
Continually improve the effectiveness of the quality management system.		
This includes determination of applicable methods, including statistical techniques, and the extent of their use.		
<b>8.2 Monitoring And Measurement</b>		
<b>8.2.1 Customer Satisfaction</b>		
As one of the measurements of the performance of the QMS, Company X monitors information relating to customer perception as to whether Company X has met customer requirements.		
The methods for obtaining and using this information has been determined.		
<b>8.2.2 Internal Audit</b>		
Internal audits are conducted at planned intervals.		
Internal audits determine whether the QMS:		
Conforms to the planned arrangements (see 7.1), to the requirements of ISO 9001 and to the QMS requirements established by Company X.		
Is effectively implemented and maintained.		
The audit programme 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.		
The audit criteria, scope, frequency & methods are defined.		
Selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process.		
Auditors do not audit their own work.		
The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records are defined in a documented procedure.		



ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.		
Follow-up activities include the verification of the actions taken and the reporting of verification results.		
<b>8.2.3 Monitoring And Measurement Of Processes</b>		
Company X applies suitable methods for monitoring and, where applicable, measurement of the QMS processes.		
These methods demonstrate the ability of the processes to achieve planned results.		
When planned results are not achieved, correction and corrective action are taken, as appropriate, to ensure conformity of the product.		
<b>8.2.4 Monitoring And Measurement Of Product</b>		
Company X monitors and measures the characteristics of the product to verify that product requirements have been met.		
This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements.		
Evidence of conformity with the acceptance criteria is maintained.		
Records indicate the person(s) authorizing release of product.		
Product release and service delivery do 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.		
<b>8.3 Control Of Nonconforming Product</b>		
Company X ensures 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 are defined in a documented procedure.		
Company X deals with nonconforming product by one or more of the following ways:		
By taking action to eliminate the detected nonconformity.		
By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer.		
By taking action to preclude its original intended use or application.		
Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained.		
When nonconforming product is corrected it is subject to re-verification to demonstrate conformity to the requirements.		
When nonconforming product is detected after delivery or use has started, the organization takes action appropriate to the effects, or potential effects, of the nonconformity.		
<b>8.4 Analysis Of Data</b>		
Company X 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. (This includes data generated as a result of monitoring and measurement and from other relevant sources)		

Customer satisfaction (see 8.2.1).		
Conformity to product requirements (see 7.2.1).		
Characteristics and trends of processes and products including opportunities for preventive action.		
Suppliers.		
<b>8.5 Improvement</b>		
<b>8.5.1 Continual Improvement</b>		
Company X continually improves 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.		
<b>8.5.2 Corrective Action</b>		
Company X takes action to eliminate the cause of nonconformities in order to prevent recurrence.		
Corrective actions are appropriate to the effects of the nonconformities encountered.		
A documented procedure is established to define requirements for:		
Reviewing nonconformities (including customer complaints).		
Determining the causes of nonconformities.		
Evaluating the need for action to ensure that nonconformities do not recur.		
Determining and implementing action needed.		
Records of the results of action taken.		
Reviewing corrective action taken.		
<b>8.5.3 Preventive Action</b>		
Company X determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence.		
Preventive actions are appropriate to the effects of the potential problems.		
A documented procedure is established to define requirements for:		
Determining potential nonconformities and their causes.		
Evaluating the need for action to prevent occurrence of nonconformities.		
Determining and implementing action needed.		
Records of results of action taken (see 4.2.4).		
Reviewing preventive action taken.		