

ISO 9001 : 2000 SELF ASSESSMENT CHECKLIST

This document restates the requirements of ISO 9001:2000 for Quality Management Systems (QMS) and has been developed to assist NCSI and its clients in the assessment of quality management systems for compliance with ISO 9001:2000.

This checklist is based on the final draft of the standard and may be subject to change after the standard is published.

This checklist presents the requirements of ISO 9001:2000 as questions and can be used as an effective tool for implementing the quality management system and for self-assessment of the system.

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<p>SCOPE OF CERTIFICATION</p> <p>What is the scope of the quality management system to be included in the certification?</p> <p>What activities and processes are not being included in the Scope of the Certification? Include justification for exclusion.</p> <p>NOTE: <i>Only activities or processes relating to Section 7 of ISO 9001:2000 can be excluded from the Scope of Certification.</i></p>	

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<p>4. Quality Management System</p> <p>4.1 General requirements</p> <p>Has the organisation established, documented, implemented and maintained a quality management system and continually improved its effectiveness in accordance with the requirements of this International Standard?</p> <p>Has the organisation:</p> <ol style="list-style-type: none"> a) Identified the processes needed for the quality management system and their application throughout the organisation; b) Determined the sequence and interaction of these processes; c) Determined criteria and methods needed to ensure that both the operation and control of these processes are effective d) Ensured the availability of resources and information necessary to support the operation and monitoring of these processes; e) Monitored, measured and analysed these processes, and f) Implemented actions necessary to achieve planned results and continual improvement of these processes? <p>Are these processes managed by the organisation in accordance with the requirements of this International Standard?</p> <p><i>Note: Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realisation and measurement.</i></p> <p>Where processes have been outsourced, has control of such processes been identified in the quality management system?</p>	

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<p>4.2 Documentation requirements</p> <p>4.2.1 General</p> <p>Does the quality management system documentation include:</p> <ul style="list-style-type: none"> a) Documented statements of quality policy and quality objectives; b) A quality manual; c) Documented procedures required by this International standard; d) Documents needed by the organisation to ensure the effective planning, operation and control of it's processes, and e) Quality records required by this International Standard? <p><i>Note 1. Where the term "documented procedure" appears, this means that the procedure is established, documented, implemented and maintained.</i></p> <p><i>Note 2. The extent of the quality management system documentation can differ from one organisation to another due to:</i></p> <ol style="list-style-type: none"> 1. <i>The size of the organisation and type of activities;</i> 2. <i>The complexity of processes and their interactions, and</i> 3. <i>The competence of personnel</i> <p><i>Note 3. The documentation can be in any form or type of medium.</i></p> <p>4.2.2 Quality manual</p> <p>Has the organisation established and maintained a quality manual that includes:</p> <ul style="list-style-type: none"> a) The scope of the quality management system, including details and justification for any exclusions b) The documented procedures established for the quality management system, or reference to them, and c) A description of the interaction between the processes of the quality management system? 	

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<p>4.2.3 Control of documents</p> <p>Are documents required by the quality management system controlled?</p> <p>Has a documented procedure defining the controls needed been established:</p> <ul style="list-style-type: none"> a) To approve documents for adequacy prior to issue; b) To review and update as necessary and re-approve documents; c) To ensure that changes and the current revision status of documents are identified d) To ensure that relevant versions of applicable documents are available at points of use; e) To ensure that documents remain legible and readily identifiable; f) To ensure that documents of external origin are identified and their distribution controlled; and g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose. <p>4.2.4 Control of quality records</p> <p>Have quality records been established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system? Are quality records legible, readily identifiable, and retrievable?</p> <p>Has a documented procedure been established that defines controls needed for the identification, storage, protection, retrieval, retention time, and disposition of quality records?</p>	

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<p data-bbox="185 271 655 300">5. Management Responsibility</p> <p data-bbox="185 336 651 365">5.1 Management commitment</p> <p data-bbox="185 387 746 551">Has management provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by</p> <ul data-bbox="185 568 807 869" style="list-style-type: none">a) Communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,b) Establishing the quality policy,c) Ensuring that quality objectives are established,d) Conducting management reviews, ande) Ensuring the availability of resources. <p data-bbox="185 1290 509 1319">5.2 Customer focus</p> <p data-bbox="185 1341 815 1469">Has top management ensured that customer requirements are determined and fulfilled with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).</p>	

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<p>5.3 Quality policy</p> <p>Has top management ensured that the quality policy</p> <ul style="list-style-type: none">a) is appropriate to the purpose of the organization,b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,c) provides a framework for establishing and reviewing quality objectives,d) is communicated and understood within the organization, ande) is reviewed for continuing suitability.	

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<p data-bbox="185 264 411 297">5.4 Planning</p> <p data-bbox="185 331 539 365">5.4.1 Quality objectives</p> <p data-bbox="185 383 794 618">Has top management ensured 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. Are the quality objectives measurable and consistent with the quality policy.</p> <p data-bbox="185 981 818 1014">5.4.2 Quality management system planning</p> <p data-bbox="185 1032 647 1066">Has top management ensured that</p> <ul data-bbox="185 1084 807 1357" style="list-style-type: none">a) The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, andb) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	

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<p>5.5 Responsibility, authority and communication</p> <p>5.5.1 Responsibility and authority</p> <p>Has top management ensured that the responsibilities, authorities and their interrelation are defined and communicated within the organization.</p> <p>5.5.2 Management representative</p> <p>Has top management appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes</p> <ul style="list-style-type: none"> a) Ensuring that processes needed for the quality management system are established, implemented and maintained, b) Reporting to top management on the performance of the quality management system and any need for improvement, and c) Ensuring the promotion of awareness of customer requirements throughout the organization. <p><i>NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.</i></p> <p>5.5.3 Internal communication</p> <p>Has top management ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.</p>	

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<p>5.6 Management review</p> <p>5.6.1 General</p> <p>Has top management reviewed the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. Has this review included assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.</p> <p>Are records from management reviews maintained (see 4.2.4).</p> <p>5.6.2 Review input</p> <p>Does input to management reviews include information on</p> <ul style="list-style-type: none"> a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) planned changes that could affect the quality management system, and g) recommendations for improvement. <p>5.6.3 Review output</p> <p>Does output from management reviews include any decisions and actions related to</p> <ul style="list-style-type: none"> a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs. 	

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<p>6. Resource Management</p> <p>6.1 Provision of resources</p> <p>Has the organization determined and provided the resources needed</p> <p>a) to implement and maintain the quality management system and continually improve its effectiveness, and</p> <p>b) to enhance customer satisfaction by meeting customer requirements.</p> <p>6.2 Human resources</p> <p>6.2.1 General</p> <p>Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience.</p> <p>6.2.2 Competence, awareness and training</p> <p>Does the organization</p> <p>a) determine the necessary competence for personnel performing work affecting product quality,</p> <p>b) provide training or take other actions to satisfy these needs,</p> <p>c) evaluate the effectiveness of the actions taken,</p> <p>d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and</p> <p>e) maintain appropriate records of education, training, skills and experience (see 4.2.4).</p>	

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<p>6.3 Infrastructure</p> <p>Has the organization determined, provided and maintained the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, for example</p> <ul style="list-style-type: none">a) buildings, workspace and associated utilities,b) process equipment, both hardware and software, andc) supporting services such as transport or communication. <p>6.4 Work environment</p> <p>Has the organization determined and managed the work environment needed to achieve conformity to product requirements.</p>	

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<p>7. Product Realization</p> <p>7.1 Planning of product realization</p> <p>Has the organization planned and developed the processes needed for product realization. Is this planning of product realization consistent with the requirements of the other processes of the quality management system (see 4.1).</p> <p>In planning product realization, has the organization determined the following, as appropriate</p> <ul style="list-style-type: none"> a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, 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 fulfil requirements (see 4.2.4). <p>Is the output of this planning 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>	

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<p>7.2 Customer-related processes</p> <p>7.2.1 Determination of requirements related to the product</p> <p>Has the organization determined</p> <ul style="list-style-type: none"> a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified use or known and intended use, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization. <p>7.2.2 Review of requirements related to the product</p> <p>Has the organization reviewed the requirements related to the product. Is this review conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and does it ensure that</p> <ul style="list-style-type: none"> e) product requirements are defined, f) contract or order requirements differing from those previously expressed are resolved, and g) the organization has the ability to meet the defined requirements. <p>Are records of the results of this review and actions arising from this review maintained (see 4.2.4).</p> <p>Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organization before acceptance.</p> <p>Where product requirements are changed, does the organization 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 advertizing material.</p>	



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<p>7.2.3 Customer communication</p> <p>Has the organization determined and implemented effective arrangements for communicating with customers in relation to</p> <ul style="list-style-type: none"> a) product information, b) enquiries, contracts or order handling, including amendments, and c) customer feedback, including customer complaints. 	

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<p>7.3 Design and development</p> <p>7.3.1 Design and development planning</p> <p>Has the organization planned and controlled the design and development of product.</p> <p>During the design and development planning, has the organization determined</p> <ul style="list-style-type: none"> a) the design and development stages, b) the review, verification and validation that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development. <p>Has the organization managed the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.</p> <p>Is planning output updated, as appropriate, as the design and development progresses.</p> <p>7.3.2 Design and development inputs</p> <p>Are inputs relating to product requirements determined and records maintained (see 4.2.4). Do they include</p> <ul style="list-style-type: none"> a) functional and performance requirements, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development. <p>Are these inputs reviewed for adequacy. Are requirements complete, unambiguous and not in conflict with each other.</p>	

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<p>7.3.3 Design and development outputs</p> <p>Are the outputs of design and development provided in a form that enables verification against the design and development input and approved prior to release.</p> <p>Design and development outputs shall</p> <ul style="list-style-type: none"> 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>7.3.4 Design and development review</p> <p>At suitable stages, are systematic reviews of design and development conducted</p> <ul style="list-style-type: none"> a) to evaluate the ability of the results of design and development to fulfil requirements, and b) to identify any problems and propose necessary actions. <p>Do participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Are records of the results of the reviews and any necessary actions maintained (see 4.2.4).</p>	

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<p>7.3.5 Design and development verification</p> <p>Is verification performed to ensure that the design and development outputs have satisfied the design and development input requirements. Are records of the results of the verification and any necessary actions maintained (see 4.2.4).</p> <p>7.3.6 Design and development validation</p> <p>Has design and development validation been performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of fulfilling the requirements for the specified or known intended use or application. Wherever practicable, is validation completed prior to the delivery or implementation of the product. Are records of the results of validation and any necessary actions maintained (see 4.2.4).</p> <p>7.3.7 Control of design and development changes</p> <p>Has design and development changes been identified and records maintained. Are the changes reviewed, verified and validated, as appropriate, and approved before implementation. Does the review of design and development changes include evaluation of the effect of the changes on constituent parts and delivered product.</p> <p>Are records of the results of the review of changes and any necessary actions maintained (see 4.2.4).</p>	

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<p>7.4 Purchasing</p> <p>7.4.1 Purchasing process</p> <p>Has the organization ensured that purchased product conforms to specified purchase requirements. Is 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 realization or the final product.</p> <p>Has the organization evaluated and selected suppliers based on their ability to supply product in accordance with the organization's requirements. Is the criteria for selection, evaluation and re-evaluation established.</p> <p>Are records of the results of evaluations and any necessary actions arising from the evaluation maintained (see 4.2.4).</p> <p>7.4.2 Purchasing information</p> <p>Purchasing information shall describe the product to be purchased, including where appropriate</p> <ul style="list-style-type: none"> a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements. <p>Has the organization ensured the adequacy of specified purchase requirements prior to their communication to the supplier.</p> <p>7.4.3 Verification of purchased product</p> <p>Has the organization established and implemented the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.</p> <p>Where the organization or its customer intends to perform verification at the supplier's premises, has the organization stated the intended verification arrangements and method of product release in the purchasing information.</p>	

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<p>7.5 Production and service provision</p> <p>7.5.1 Control of production and service provision</p> <p>Has the organization planned and carried out production and service provisions under controlled conditions. Do these controlled conditions include, as applicable</p> <ul style="list-style-type: none"> a) the availability of information that describes the characteristics of the product, b) the availability of work instructions, 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>7.5.2 Validation of processes for production and service provision</p> <p>Has the organization validated any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. Does this include any processes where deficiencies become apparent only after the product is in use or the service has been delivered.</p> <p>Does validation demonstrate the ability of these processes to achieve planned results.</p> <p>Has the organization established arrangements for these processes including, as applicable</p> <ul style="list-style-type: none"> a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures, d) requirements for records (see 4.2.4), and e) revalidation. 	

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<p>7.5.3 Identification and traceability</p> <p>Where appropriate, has the organization identified the product by suitable means throughout product realization.</p> <p>Has the organization identified the product status with respect to monitoring and measurement requirements.</p> <p>Where traceability is a requirement, has the organization controlled and recorded the unique identification of the product (see 4.2.4).</p> <p>NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained.</p> <p>7.5.4 Customer property</p> <p>Has the organization exercised care with customer property while it is under the organization's control or being used by the organization. Has the organization identified, verified, protected and safeguarded 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 maintained (see 4.2.4).</p> <p>NOTE: Customer property can include intellectual property.</p> <p>7.5.5 Preservation of product</p> <p>Has the organization preserved the conformity of product during internal processing and delivery to the intended destination. Does this preservation include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.</p>	

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<p>7.6 Control of monitoring and measuring devices</p> <p>Has the organization determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).</p> <p>Has the organization 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.</p> <p>Where necessary to ensure valid results, is measuring equipment:</p> <ol style="list-style-type: none"> a) 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; b) adjusted or re-adjusted as necessary; c) identified to enable the calibration status to be determined; d) safeguarded from adjustments that would invalidate the measurement result; e) protected from damage and deterioration during handling, maintenance and storage. <p>In addition, has the organization assessed and recorded the validity of the previous measuring results when the equipment is found not to conform to requirements. Has the organization taken appropriate action on the equipment and any product affected. Are records of the results of calibration and verification maintained (see 4.2.4).</p> <p>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 necessary.</p> <p>NOTE: See ISO 10012-1 and ISO 10012-2 for guidance.</p>	

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<p data-bbox="183 271 655 331">8. Measurement, Analysis and Improvement</p> <p data-bbox="183 369 395 398">8.1 General</p> <p data-bbox="183 421 810 517">Has the organization planned and implemented the monitoring, measurement, analysis and improvement processes needed</p> <ul data-bbox="183 539 799 719" style="list-style-type: none">a) to demonstrate conformity of the product,b) to ensure conformity of the quality management system, andc) to continually improve the effectiveness of the quality management system. <p data-bbox="183 763 783 860">Does this include determination of applicable methods, including statistical techniques, and the extent of their use.</p> <p data-bbox="183 1173 699 1202">8.2 Monitoring and measurement</p> <p data-bbox="183 1240 595 1270">8.2.1 Customer satisfaction</p> <p data-bbox="183 1292 826 1523">As one of the measurements of the performance of the quality management system, does the organization monitor information relating to customer perception as to whether the organization has fulfilled customer requirements. Are the methods for obtaining and using this information determined</p>	

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<p>8.2.2 Internal audit</p> <p>Has the organization conducted internal audits at planned intervals to determine whether the quality management system</p> <p>a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and</p> <p>b) is effectively implemented and maintained.</p> <p>Has an audit programme been planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. Is the audit criteria, scope, frequency and methods defined. Does the selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process.</p> <p>Do auditors audit their own work. Are the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) defined in a documented procedure.</p> <p>Has the management responsible for the area being audited ensured that actions are taken without undue delay to eliminate detected nonconformities and their causes. Do follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2).</p> <p>NOTE: See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.</p>	

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<p>8.3 Control of nonconforming product</p> <p>Has the organization ensured that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. Are these controls and related responsibilities and authorities for dealing with nonconforming product defined in a documented procedure.</p> <p>Has the organization dealt with nonconforming product by one or more of the following ways:</p> <ul style="list-style-type: none"> a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer; c) by taking action to preclude its original intended use or application. <p>Are records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, maintained (see 4.2.4).</p> <p>When nonconforming product is corrected, is it subject to re-verification to demonstrate conformity to the requirements.</p> <p>When nonconforming product is detected after delivery or use has started, does the organization take action appropriate to the effects, or potential effects, of the nonconformity.</p>	

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<p>8.4 Analysis of data</p> <p>Has the organization determined, collected and analysed appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. Does this include data generated as a result of monitoring and measurement and from other relevant sources.</p> <p>Does the analysis of data provide information relating to</p> <ul style="list-style-type: none">a) customer satisfaction (see 8.2.1),b) conformance to product requirements (see 7.2.1),c) characteristics and trends of processes and products including opportunities for preventive action, andd) suppliers.	

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<p>8.5 Improvement</p> <p>8.5.1 Continual improvement</p> <p>Has the organization continually improved 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>8.5.2 Corrective action</p> <p>Has the organization taken action to eliminate the cause of nonconformities in order to prevent recurrence. Are corrective actions appropriate to the effects of the nonconformities encountered.</p> <p>Is a documented procedure established to define requirements for</p> <ul style="list-style-type: none"> a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities , c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, e) records of the results of action taken (see 4.2.4), and f) reviewing corrective action taken. 	

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<p>8.5.3 Preventive action</p> <p>Has the organization determined action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Are these preventive actions appropriate to the effects of the potential problems.</p> <p>A documented procedure shall be established to define requirements for</p> <ul style="list-style-type: none">a) determining potential nonconformities and their causes,b) evaluating the need for action to prevent occurrence of nonconformities,c) determining and implementing action needed,d) records of results of action taken (see 4.2.4), ande) reviewing preventative action taken.	