

ISO 9001: 2000 (December 13,2000)
QUALITY MANAGEMENT SYSTEM DOCUMENTATION OVERVIEW MATRIX

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
4 Quality management system		
4.1 General requirements		
	4.1	The organization shall establish, document, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of International Standard ISO 9001:2000.
	4.1.a	The organization shall identify the processes needed for the quality management system and their application throughout the organization (see1.2).
	4.1.b	The organization shall determine the sequence and interaction of these processes.
	4.1.c	The organization shall determine criteria and methods needed to ensure that both the operation and control of these processes are effective.
	4.1.d	The organization shall ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
	4.1.e	The organization shall monitor, measure and analyze these processes.
	4.1.f	The organization shall implement actions necessary to achieve planned results and continual improvement of these processes.
	4.1	These processes shall be managed by the organization in accordance with the requirements of International Standard ISO 9001:2000.
	4.1	Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes.
	4.1	Control of such outsourced processes shall be identified within the quality management system.
Caution: This note is to aid implementation.	NOTE	Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.
4.2 Documentation requirements		
4.2.1 General		
	4.2.1.a	The quality management system documentation shall include documented statements of a quality policy and quality objectives.
	4.2.1.b	The quality management system documentation shall include a quality manual.
	4.2.1.c	The quality management system documentation shall include documented procedures required by ISO 9001: 2000.
	4.2.1.d	The quality management system documentation shall include documents needed by the organization to ensure the effective planning, operation and control of its processes.
	4.2.1.e	The quality management system documentation shall include records required by ISO 9001: 2000.
Caution: This note is to aid implementation.	NOTE 1	Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.
Caution: This note is to aid implementation.	NOTE 2	The extent of the quality management system documentation can differ from one organization to another due to: a) the size of organization and type of activities, b) the complexity of the processes and their interactions, and c) the competence of personnel.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
Caution: This note is to aid implementation.	NOTE 3	The documentation can be in any form or type of medium.
4.2.2 Quality manual		
	4.2.2.a	The organization shall establish and maintain a quality manual that includes the scope of the quality management system, including details of and justification for any exclusions (see 1.2)
	4.2.2.b	The organization shall establish and maintain a quality manual that includes the documented procedures established for the quality management system, or reference to them.
	4.2.2.c	The organization shall establish and maintain a quality manual that includes a description of the interaction between the processes of the quality management system.
4.3.2 Control of documents		
	4.2.3	Documents required by the quality management system shall be controlled.
	4.2.3	Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.
	4.2.3.a	A documented procedure shall be established to define the controls needed to approve documents for adequacy prior to issue.
	4.2.3.b	A documented procedure shall be established to define the controls needed to review and update as necessary and re-approve documents.
	4.2.3.c	A documented procedure shall be established to define the controls needed to ensure that changes and the current revision status of documents are identified.
	4.2.3.d	A documented procedure shall be established to define the controls needed to ensure that relevant versions of applicable documents are available at points of use.
	4.2.3.e	A documented procedure shall be established to define the controls needed to ensure that documents remain legible and readily identifiable.
	4.2.3.f	A documented procedure shall be established to define the controls needed to ensure that documents of external origin are identified and their distribution controlled.
	4.2.3.g	A documented procedure shall be established to define the controls needed to 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		
	4.2.4	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.
	4.2.4	Records shall remain legible, readily identifiable and retrievable.
	4.2.4	A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.
5 Management Responsibility		
5.1 Management commitment		
	5.1.a	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	5.1.b	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by establishing the quality policy.
	5.1.c	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by ensuring that quality objectives are established.
	5.1.d	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by conducting management reviews.
	5.1.e	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by ensuring the availability of resources.
5.2 Customer focus		
	5.2	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).
5.3 Quality policy		
	5.3.a	Top management shall ensure that the quality policy is appropriate to the purpose of the organization.
	5.3.b	Top management shall ensure that the quality policy includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system.
	5.3.c	Top management shall ensure that the quality policy provides a framework for establishing and reviewing quality objectives.
	5.3.d	Top management shall ensure that the quality policy is communicated and understood within the organization.
	5.3.e	Top management shall ensure that the quality policy is reviewed for continuing suitability.
5.4 Planning		
5.4.1 Quality objectives		
	5.4.1	Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1.a], are established at relevant functions and levels within the organization.
	5.4.1	The quality objectives shall be measurable and consistent with the quality policy.
5.4.2 Quality management system planning		
	5.4.2.a	Top management shall ensure that 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.
	5.4.2.b	Top management shall ensure that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
5.5 Responsibility, authority and communication		
5.5.1 Responsibility and authority		
	5.5.1	Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.
5.5.2 Management representative		
	5.5.2.a	Top management shall appoint a member of the management who, irrespective of other responsibilities, shall have responsibility and authority that includes ensuring that processes needed for the quality management system are established, implemented and maintained.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	5.5.2.b	Top management shall appoint a member of the management who, irrespective of other responsibilities, shall have responsibility and authority that includes reporting to top management on the performance of the quality management system and any need for improvement.
	5.5.2.c	Top management shall appoint a member of the management who, irrespective of other responsibilities, shall have responsibility and authority that includes ensuring the promotion of awareness of customer requirements throughout the organization.
Caution: This note is to aid implementation.	NOTE	The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.
5.5.3 Internal communication		
	5.5.3	Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.
5.6 Management review		
5.6.1 General		
	5.6.1	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.
	5.6.1	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.
	5.6.1	Records from management reviews shall be maintained (see 4.2.4).
5.6.2 Review Input		
	5.6.2.a	Inputs to management review shall include information on results of audits.
	5.6.2.b	Inputs to management review shall include information on customer feedback.
	5.6.2.c	Inputs to management review shall include information on process performance and product conformity.
	5.6.2.d	Inputs to management review shall include information on status of preventive and corrective actions.
	5.6.2.e	Inputs to management review shall include information on follow-up actions from previous management reviews.
	5.6.2.f	Inputs to management review shall include information on changes that could affect the quality management system.
	5.6.2.g	Inputs to management review shall include information on recommendations for improvement.
5.6.3 Review output		
	5.6.3.a	The output from a management review shall include any decisions and actions related to improvement of the effectiveness of the quality management system and its processes.
	5.6.3.b	The output from a management review shall include any decisions and actions related to improvement of product related to customer requirements.
	5.6.3.c	The output from a management review shall include any decisions and actions related to resource needs.
6 Resource management		
6.1 Provision of resources		

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	6.1.a	The organization shall determine and provide the resources needed to implement and maintain the quality management system and continually improve its effectiveness.
	6.1.b	The organization shall determine and provide the resources needed to enhance customer satisfaction by meeting customer requirements.
6.2 Human resources		
6.2.1 General		
	6.2.1	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.
6.2.2 Competence, awareness and training		
	6.2.2.a	The organization shall determine the necessary competence for personnel performing work affecting product quality.
	6.2.2.b	The organization shall provide training or take other actions to satisfy these needs.
	6.2.2.c	The organization shall evaluate the effectiveness of actions taken.
	6.2.2.d	The organization shall 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.
	6.2.2.e	The organization shall maintain appropriate records of education, training, skills and experience (see 4.2.4).
6.3 Infrastructure		
	6.3	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable: a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).
6.4 Work environment		
	6.4	The organization shall determine and manage the work environment needed to achieve conformity to product requirements.
7 Product realization		
7.1 Planning of product realization		
	7.1	The organization shall plan and develop the processes needed for product realization.
	7.1	Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).
	7.1.a	In planning product realization, the organization shall determine the following, as appropriate: quality objectives and requirements for the product.
	7.1.b	In planning product realization, the organization shall determine the following, as appropriate: the need to establish processes, documents and provide resources specific to the product.
	7.1.c	In planning product realization, the organization shall determine the following, as appropriate: required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance.
	7.1.d	In planning product realization, the organization shall determine the following, as appropriate: records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).
	7.1	The output of this planning shall be in a form suitable for the organization's method of operations.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
Caution: This note is to aid implementation.	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.
Caution: This note is to aid implementation.	NOTE 2	The organization may also apply the requirements given in 7.3 to the development of product realization processes.
7.2 Customer-related processes		
7.2.1 Determination of requirements related to the product		
	7.2.1.a	The organization shall determine requirements specified by the customer, including the requirements for delivery and post-delivery activities.
	7.2.1.b	The organization shall determine requirements not stated by the customer but necessary for specified or intended use, where known.
	7.2.1.c	The organization shall determine statutory and regulatory requirements related to the product.
	7.2.1.d	The organization shall determine any additional requirements determined by the organization.
7.2.2 Review of requirements related to the product		
	7.2.2	The organization shall review the requirements related to the product.
	7.2.2.a	This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that product requirements are defined.
	7.2.2.b	This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that contract or order requirements differing from those previously expressed are resolved.
	7.2.2.c	This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that the organization has the ability to meet the defined requirements.
	7.2.2	Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).
	7.2.2	Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.
	7.2.2	Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.
Caution: This note is to aid implementation.	NOTE	In some situations, such as Internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.
7.2.3 Customer communication		
	7.2.3.a	The organization shall determine and implement effective arrangements for communicating with customers relating to product information.
	7.2.3.b	The organization shall determine and implement effective arrangements for communicating with customers relating to inquiries, contracts or order handling, including amendments.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	7.2.3.c	The organization shall determine and implement effective arrangements for communicating with customers relating to customer feedback, including customer complaints.
7.3 Design and development		
7.3.1 Design and development planning		
	7.3.1	The organization shall plan and control the design and development of product.
	7.3.1.a	During the design and development planning, the organization shall determine the design and development stages.
	7.3.1.b	During the design and development planning, the organization shall determine the review, verification and validation that are appropriate to each design and development stage.
	7.3.1.c	During the design and development planning, the organization shall determine the responsibilities and authorities for design and development.
	7.3.1	The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.
	7.3.1	Planning output shall be updated, as appropriate, as the design and development progresses.
7.3.2 Design and development inputs		
	7.3.2	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4).
	7.3.2.a	These inputs shall include functional and performance requirements.
	7.3.2.b	These inputs shall include applicable statutory and regulatory requirements.
	7.3.2.c	These inputs shall include where applicable, information derived from previous similar designs.
	7.3.2.d	These inputs shall include other requirements essential for design and development.
	7.3.2	These inputs shall be reviewed for adequacy.
	7.3.2	Requirements shall be complete, unambiguous and not in conflict with each other.
7.3.3 Design and development outputs		
	7.3.3	The outputs of the design and development shall be provided in a form that enables verification against the design and development input.
	7.3.3	The outputs of the design and development shall be approved prior to release.
	7.3.3.a	Design and development outputs shall meet the input requirements for design and development.
	7.3.3.b	Design and development outputs shall provide appropriate information for purchasing, production and for service provision.
	7.3.3.c	Design and development outputs shall contain or reference product acceptance criteria.
	7.3.3.d	Design and development outputs shall specify the characteristics of the product that are essential for its safe and proper use.
7.3.4 Design and development review		

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	7.3.4.a	At suitable stages, systematic reviews of the design and development shall be performed in accordance with planned arrangements (see 7.3.1) to evaluate the ability to evaluate the ability of the results of design and development to meet requirements.
	7.3.4.b	At suitable stages, systematic reviews of the design and development shall be performed in accordance with planned arrangements (see 7.3.1) to identify any problems and propose necessary actions.
	7.3.4	Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed.
	7.3.4	Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).
7.3.5 Design and development verification		
	7.3.5	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements.
	7.3.5	Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).
7.3.6 Design and development validation		
	7.3.6	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known.
	7.3.6	Wherever practicable, validation shall be completed prior to the delivery or implementation of the product.
	7.3.6	Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).
7.3.7 Control of design and development changes		
	7.3.7	Design and development changes shall be identified and records maintained.
	7.3.7	The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation.
	7.3.7	The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.
	7.3.7	Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).
7.4 Purchasing		
7.4.1 Purchasing process		
	7.4.1	The organization shall ensure that purchased product conforms to specified purchase requirements.
	7.4.1	The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
	7.4.1	The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements.
	7.4.1	Criteria for selection, evaluation and re-evaluation shall be established.
	7.4.1	Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).
7.4.2 Purchasing information		

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	7.4.2.a	Purchasing information shall describe the product to be purchased, including where appropriate requirements for approval product, procedures, processes and equipment.
	7.4.2.b	Purchasing information shall describe the product to be purchased, including where appropriate requirements for qualification of personnel.
	7.4.2.c	Purchasing information shall describe the product to be purchased, including where appropriate quality management system requirements.
	7.4.2	The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.
7.4.3 Verification of purchased product		
	7.4.3	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.
	7.4.3	Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.
7.5 Production and service operations		
7.5.1 Control of production and service provision		
	7.5.1	The organization shall plan and carry out production and service provision under controlled conditions.
	7.5.1.a	Controlled conditions shall include, as applicable the availability of information that describes the characteristics of the product.
	7.5.1.b	Controlled conditions shall include, as applicable the availability of work instructions, as necessary.
	7.5.1.c	Controlled conditions shall include, as applicable the use of suitable equipment.
	7.5.1.d	Controlled conditions shall include, as applicable the availability and use of monitoring and measuring devices.
	7.5.1.e	Controlled conditions shall include, as applicable the implementation of monitoring and measurement.
	7.5.1.f	Controlled conditions shall include, as applicable the implementation of release, delivery and post-delivery activities.
7.5.2 Validation of processes for production and service provision		
	7.5.2	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is used or the service has been delivered.
	7.5.2	Validation shall demonstrate the ability of these processes to achieve planned results.
	7.5.2.a	The organization shall establish arrangements for these processes including, as applicable defined criteria for review and approval of the processes.
	7.5.2.b	The organization shall establish arrangements for these processes including, as applicable approval of equipment and qualification of personnel.
	7.5.2.c	The organization shall establish arrangements for these processes including, as applicable use of specific methods and procedures.
	7.5.2.d	The organization shall establish arrangements for these processes including, as applicable requirements for records (see 4.2.4).
	7.5.2.e	The organization shall establish arrangements for these processes including, as applicable revalidation.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
7.5.3 Identification and traceability		
	7.5.3	Where appropriate, the organization shall identify the product by suitable means throughout product realization.
	7.5.3	The organization shall identify the product status with respect to monitoring and measurement requirements.
	7.5.3	Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).
Caution: This note is to aid implementation.	NOTE	In some industry sectors, configuration management is a means by which identification and traceability are maintained.
7.5.4 Customer property		
	7.5.4	The organization shall exercise care with customer property while it is under the organization's control or being used by the organization.
	7.5.4	The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product.
	7.5.4	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 (see 4.2.4).
Caution: This note is to aid implementation.	NOTE	Customer property can include intellectual property.
7.5.5 Preservation of product		
	7.5.5	The organization shall preserve the conformity of product during internal processing and delivery to the intended destination.
	7.5.5	This preservation shall include identification, handling, packaging, storage and protection.
	7.5.5	Preservation shall also apply to the constituent parts of a product.
7.6 Control of monitoring and measuring devices		
	7.6	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).
	7.6	The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the calibrated, monitoring and measurement requirements.
	7.6.a	Where necessary to ensure valid results, measuring equipment shall be calibrate 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.
	7.6.b	Where necessary to ensure valid results, measuring equipment shall be adjusted or re-adjusted as necessary.
	7.6.c	Where necessary to ensure valid results, measuring equipment shall be identified to enable the calibration status to be determined.
	7.6.d	Where necessary to ensure valid results, measuring equipment shall be safeguarded from adjustments that would invalidate the measurement result.
	7.6.e	Where necessary to ensure valid results, measuring equipment shall be protected from damage and deterioration during handling, maintenance and storage.
	7.6	In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	7.6	The organization shall take appropriate action on the equipment and any product affected.
	7.6	Records of the results of calibration and verification shall be maintained (see 4.2.4).
	7.6	When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed.
	7.6	This shall be undertaken prior to initial use and reconfirmed as necessary.
Caution: This note is to aid implementation.	NOTE	See ISO 10012-1 and ISO 10012-2 for guidance.
8 Measurement, analysis and improvement		
8.1 General		
	8.1.a	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product.
	8.1.b	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to ensure conformity of the quality management system.
	8.1.c	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to continually improve the effectiveness of the quality management system.
	8.1	This shall include determination of applicable methods, including statistical techniques, and the extent of their use.
8.2 Monitoring and measurement		
8.2.1 Customer satisfaction		
	8.2.1	As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements.
	8.2.1	The methods for obtaining and using this information shall be determined.
8.2.2 Internal audit		
	8.2.2.a	The organization shall conduct internal audits at planned intervals to determine whether the quality management system 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.
	8.2.2.b	The organization shall conduct internal audits at planned intervals to determine whether the quality management system is effectively implemented and maintained.
	8.2.2	An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of the previous audits.
	8.2.2	The audit criteria, scope, frequency and methods shall be defined.
	8.2.2	Selection of auditors and conduct of the audits shall ensure objectivity and impartiality of the audit process.
	8.2.2	Auditors shall not audit their own work.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	8.2.2	The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.
	8.2.2	The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.
	8.2.2	Follow-up actions shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).
Caution: This note is to aid implementation.	NOTE	See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.
8.2.3 Monitoring and measurement of process		
	8.2.3	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.
	8.2.3	These methods shall demonstrate the ability of the processes to achieve planned results.
	8.2.3	When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.
8.2.4 Monitoring and measurement of product		
	8.2.4	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met.
	8.2.4	This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).
	8.2.4	Evidence of conformity with the acceptance criteria shall be maintained.
	8.2.4	Records shall indicate the person(s) authorizing release of product (see 4.2.4).
	8.2.4	Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.
8.3 Control of nonconforming product		
	8.3	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.
	8.3	The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.
	8.3.a	The organization shall deal with nonconforming product by one or more of the following ways: by taking action to eliminate the detected nonconformity.
	8.3.b	The organization shall deal with nonconforming product by one or more of the following ways: by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer.
	8.3.c	The organization shall deal with nonconforming product by one or more of the following ways: by taking action to preclude its original intended use or application.
	8.3	Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).
	8.3	When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.
	8.3	When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
8.4 Analysis of data		
	8.4	The organization shall determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made.
	8.4	This shall include data generated as a result of monitoring and measurement and from other relevant sources.
	8.4.a	The analysis of data shall provide information relating to customer satisfaction (see 8.2.1).
	8.4.b	The analysis of data shall provide information relating to conformity to product requirements (see 7.2.1).
	8.4.c	The analysis of data shall provide information relating to characteristics and trends of processes and products including opportunities for preventive action.
	8.4.d	The analysis of data shall provide information relating to suppliers.
8.5 Improvement		
8.5.1 Continual Improvement		
	8.5.1	The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
8.5.2 Corrective action		
	8.5.2	The organization shall take corrective action to eliminate the cause of nonconformities in order to prevent recurrence.
	8.5.2	Corrective actions shall be appropriate to the effects of the nonconformities encountered.
	8.5.2.a	A documented procedure shall be established to define requirements for reviewing nonconformities (including customer complaints).
	8.5.2.b	A documented procedure shall be established to define requirements for determining the causes of nonconformities.
	8.5.2.c	A documented procedure shall be established to define requirements for evaluating the need for action to ensure that nonconformities do not recur.
	8.5.2.d	A documented procedure shall be established to define requirements for determining and implementing action needed.
	8.5.2.e	A documented procedure shall be established to define requirements for records of the results of action taken (see 4.2.4).
	8.5.2.f	A documented procedure shall be established to define requirements for reviewing corrective action taken.
8.5.3 Preventive action		
	8.5.3	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.
	8.5.3	Preventive actions shall be appropriate to the effects of the potential problems.
	8.5.3.a	A documented procedure shall be established to define requirements for determining potential nonconformities and their causes.
	8.5.3.b	A documented procedure shall be established to define requirements for evaluating the need for action to prevent occurrence of nonconformities.
	8.5.3.c	A documented procedure shall be established to define requirements for determining and implementing action needed.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	8.5.3.d	A documented procedure shall be established to define requirements for records of results of action taken (see 4.2.4).
	8.5.3.e	A documented procedure shall be established to define requirements for reviewing preventive action taken.

Submit this with a controlled copy of your documentation to Entela, QSRD for evaluation. A report will be prepared and closure to any nonconformances documented must be submitted and accepted prior to the initial audit.

ISO Management Representative: _____ e-mail: _____

Your Company Name: _____ Phone: _____

Your Site/Company Address: _____ Fax: _____

Your Site/Company City, State Zip _____

Date & Revision of Policy Manual (Level I): _____

- Submitted Hard Copy
- Submitted electronic

Date & Revision of Procedure Manual (Level II): _____

- Submitted
- Not Submitted

Date & Revision of Work Instructions Manual (Level III): _____

- Submitted
- Not Submitted

Sent to: Document Review
Entela, QSRD
2625 Buchanan SW
Grand Rapids, MI 49548-1206

Questions: Phone (616) 222-7979