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

In completing your Documented Quality Management System Review, it is important that the following matrix be completed and returned to us as soon as possible. This will save time during the review and act as a checklist to you, the client, to ensure that no aspect of the applicable ISO 9001:2000 standard has been ignored. Occasionally, a particular clause of the standard may not be applicable to the client organization in which case, "N/A" should be noted in the appropriate column. Please note however for ISO 9001:2000 the only clause that may be "N/A" is relative to servicing for design responsible suppliers and possibly design and/or servicing for non-design responsible suppliers.

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.

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)
	4.2.1.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.
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.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	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.
	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 [see7.1.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		

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)
	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.
	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.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	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		
	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.

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)
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.
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.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	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.
	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.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	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		
	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).

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
		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
	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.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	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.
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		

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	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.
	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.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	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.
	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.

Referenced In Company Documentation	Section Of ISO 9001:2000	Requirements of ISO 9001: 2000 (December 13, 2000)
	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 s**hall** take action appropriate to the effects, or potential effects, of the nonconformity.
		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.

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)
	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.
	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 your registrar 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: _____

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

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