

**ISO 9001 (2000) QUALITY MANAGEMENT SYSTEM ASSESSMENT REPORT
SUPPLIER/ SUBCONTRACTOR**

SUPPLIER/ SUBCONTRACTOR NAME: _____

ADDRESS: _____

CITY AND STATE: _____

ZIP CODE: _____

SUPPLIER/MANUFACTURER NO _____

PHONE: _____

DIVISION: _____

REQUESTED BY: _____

EVALUATOR: _____

EVALUATION DATE: _____

CHECKLIST INSTRUCTIONS

1. All checklist line items within each element must be answered in sufficient detail to permit evaluation of compliance.
 2. Enter an "X" in the appropriate spaces. (Refer to the COM, MIN and MJR definitions on page one of the checklist). List procedure numbers and paragraph numbers in the comments column.
 4. A separate comment sheet may be used to supplement the checklist comments column. (Enter corresponding reference comment numbers).
 5. When supplemental data is required, reference it in the in the comments column.
 6. Submittal of an incomplete checklist will be cause for delay in completing the evaluation.
-

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	

4.1 General Requirements

	A quality management system has been established, documented, implemented, maintained, and continually improved?				
Does the quality management system include:					
	a. Identification of the processes needed for the quality management system and their application?				
	b. Determination of the sequence and interaction of these processes?				
	c. Determined criteria and methods required ensuring the effective operation and control of these processes?				
	d. The availability of information necessary to support the operation and monitoring of these processes?				
	e. Methods to measure monitor and analyze these processes?				
	f. Implemented action necessary to achieve planned results and continual improvement?				
	Are processes that are outsourced that may affect product or service conformity identified and documented?				

4.2.1 General Documentation Requirements

	Does the quality management system documentation include documented procedures and records required ensuring effective operation and control of its processes?				
	Is the extent of the quality management system documentation appropriate to:				
	a. Size and type of the organization?				
	b. Complexity and interaction of the processes?				
	c. Competence of personnel?				

Does the quality system documentation include:

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	a. A documented quality policy and quality objectives				
	b. A quality manual?				
	c. Documented procedures required by ISO 9001:2000?				
	d. Documents required by the organization?				
	e. Quality records required by ISO 9001:2000?				

4.2.2 Quality Manual

Has a quality manual been established which includes:

	a. Scope of quality system, including details and justifications for exclusions?				
	b. Procedures or references to procedures?				
	c. Sequence and interaction of QMS processes or reference to them?				

4.2.3 Control of Documents

	Are documents required for the quality management system controlled?				
--	--	--	--	--	--

Is there a documented procedure for:

	a. The approval of documents for adequacy prior to issue?				
	b. The review, updating as necessary and re-approval of documents?				
	c. The identification of the current revision status of documents?				
	d. Ensuring that relevant versions of applicable documents are available at points of use?				

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	f. For ensuring that documents of external origin are identified and their distribution is controlled?				
	e. For ensuring that documents remain legible, readily identifiable and retrievable?				
	g. Preventing the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose?				

4.2.4 Control of Records

	Are quality records for resources and system planning available?				
	Do these records provide evidence of conformance to requirements and of effective operation of the quality management system?				
	Are records legible, readily identifiable and retrievable?				
	Is there a documented procedure that defines the controls needed for identification, storage, retrieval, protection, retention time and disposition of records.				

5.1 Management Commitment

	How has top management demonstrated commitment to the development and improvement of the quality management system?				
	a. Communicating to the organization the importance of meeting customer as well as regulatory & legal requirements?				
	b. Establishing the quality policy?				
	c. Ensuring that quality objectives are established?				
	d. Conducting management reviews?				
	e. Ensuring the availability of resources?				

5.2 Customer Focus

	Does top management ensure that customer requirements are determined and fulfilled with the aim of achieving customer satisfaction?				
--	---	--	--	--	--

5.3 Quality Policy

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	

Has as top management ensured that the quality policy:

	Is appropriate to the purpose of the organization?				
	b. Includes a commitment to meeting requirements and to continual improvement?				
	c. Provides a framework for establishing and reviewing quality objectives?				
	d. Is communicated and understood at within the organization?				
	e. Is reviewed for continuing suitability?				

5.4 Planning

5.4.1 Quality Objectives

	What are the quality objectives that have been established at relevant functions and levels within the organization?				
	Are the quality objectives measurable and consistent with the quality policy?				
	Do quality objectives include those needed to meet requirements for product/service?				

5.4.2 Quality Management System Planning

How has Top Management ensured that:

	a. Processes of the quality management system are carried out in order to meet the requirements?				
	b. Is the output of quality planning documented? How?				
	c. A changes conducted in a controlled manner and is the integrity of the QMS maintained during changes?				
	d. How and what method is used when planning changes that may affect the quality management system?				

5.5 Responsibility, authority and Communication

5.5.1 Responsibility and authority

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	How are the functions and their interrelations within the organization, including responsibilities and authorities, defined and communicated?				
	How is responsibility and authority defined?				

5.5.2 Management representative

	Has top management appointed a member of management that has the responsibility and authority that includes:				
	a. ensuring that processes needed for the QMS are established, implemented and maintained?				
	b. reporting to top management on the performance of the QMS and any need for changes.				
	c. ensuring the promotion of awareness of customer requirements throughout the organization.				

5.5.3 Internal Communications

	What communication channels have been established within the organization relating to quality management system effectiveness?				

5.6 General - Management Review

	Does top management review the quality management system, at planned intervals, to ensure its continuing Suitability, adequacy, and effectiveness?				
	What is the interval?				
	Does the review evaluate the need for changes to the quality management system, including quality policy and quality objectives?				
	How are opportunities for improvement and changes needed within the quality system evaluated and documented?				

5.6.2 Review Input

Do inputs to management review include current performance and improvement opportunities related to the following:

	a. Results of audits?				
	b. Customer feedback?				
	c. Process performance and product conformance?				

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	d. Status of preventive and corrective actions?				
	e. Follow-up actions from earlier management reviews?				
	f. Planned changes that could affect the quality management system?				
	g. Recommendations for improvement?				

5.6.3 Review Output

	Do outputs to management review include current performance and improvement opportunities related to the following:				
	a. Improvements of the effectiveness of the QMS and its processes?				
	b. Improvement of product or service related to customer requirements?				
	c. Resource needs?				

6 Resource Management

6.1 Provision of resources

	How have resources needed to implement and improve quality management system processes been provided?				
	Are there adequate resources available to implement and maintain the QMS and to continually improve its effectiveness?				
	Are resources available to ensure that customer satisfaction is enhanced?				
	Are there defined responsibilities and authorities of all personnel who can affect quality?				

6.2.2 Competence, Awareness and Training

	Are personnel assigned responsibilities in the quality management systems qualified and deemed competent based on skills, experience, and education & training requirements ?				
--	---	--	--	--	--

How has the organization:

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	a. Determined the necessary competency for personnel?				
	b. Provided training to satisfy competency needs?				
	c. Evaluated the effectiveness of actions taken?				
	d. Ensured that its personnel are aware of their part in the QMS?				
	e. Maintained appropriate records of education, training, skills, and experience?				

6.3 Infrastructure

Is the infrastructure of the organization such that:

	a. Buildings, workspace, and associated utilities are determined, provided, and maintained?				
	b. Process equipment, hardware, and software are determined, provided, and maintained?				
	c. Supporting services such as transportation or communication are determined, provided, and maintained?				

6.4 Work Environment

	Does the organization identify and manage the human and physical factors of the work environment needed to achieve conformity of product/service?				
--	---	--	--	--	--

7.1 Planning of Product (Service) Realization

	Is planning of the realization processes consistent with the other requirements of the organization's quality management system?				
	Are realization processes documented in a form suitable for the organization's method of service deliver and/or operation?				

In planning product realization, has the organization determined:

	a. That quality objectives and requirements for the product, service?				
	b. The need to establish processes and documents, and provide resources specific to the product/service?				

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	c. That verification, validation, monitoring, inspection and test activities, and the criteria for product/service acceptability?				
	d. The records that are necessary to provide evidence of conformity of the processes and resulting product/service fulfill customer requirements?				

7.2 Customer Related Process

7.2.1 Determination of Requirements Related to the Product/Service

	Has the organization determined customer requirements including:				
	a. Product/service delivery requirements specified by the customer (including post delivery activities if any)?				
	b. Product/service delivery requirements not specified by the customer but necessary for intended or specified use?				
	c. Obligations related to product, including regulatory and legal requirements?				
	d. Additional requirements determined by the organization?				

7.2.2 Review of Requirements Related to the Product (Service)

	Does the organization review the identified requirements together with additional requirements determined by the organization prior to acceptance?				
	Is this review conducted prior to the commitment to supply a product to the customer?				

Does the review ensure that:

	a. Product/service delivery requirements are defined?				
	b. Where the customer provides no documented statement of requirement, the customer requirements are confirmed before acceptance?				
	c. Contract or order requirements differing from those previously expressed are resolved?				
	d. The organization has the ability to meet defined requirements?				
	Are the results of the review, actions, and subsequent follow up actions recorded (see ISO Element 4.2.4)?				

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	Where product/service requirements are changed, does the organization ensure that relevant documentation is amended?				
	How are verbal orders handled, addressed, and documented?				
	Does the organization ensure that relevant personnel are made aware of the changed requirement?				
	How are customer requirements reviewed before services are provided?				
	How are the results of the review of agreements and any follow-up actions recorded?				

7.2.3 Customer Communication

How does the organization identify and implement arrangements for communication with Customers relating to:

	a. Product information?				
	b. Inquiries, contracts, or order handling, including amendments?				
	c. Customer feedback, including customer complaints?				

7.3.1

& Design and Development Planning and Design and Development Inputs

7.3.2

	What is the design and development planning methodology described in the design procedure?				
	How are the design and development stages planned and organized?				
	Who is responsible to review, verify and validate each design and development stage?				
	How are the interfaces between different groups involved in design identified and managed?				
	Are design and development inputs relating to product requirements defined and documented?				

Do these inputs include:

	a. functional and performance requirements?				
--	---	--	--	--	--

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	b. Applicable statutory and regulatory requirements?				
	c. Where applicable, information derived from previous similar designs?				
	d. Other requirements essential for design and development?				

7.3.3 Design and Development Outputs

	Are the outputs of the design and/or development process documented in a manner that enables verification against the design and/or development inputs?				
--	---	--	--	--	--

Does design and/or development output:

	a. Meet the design and/or development input requirements?				
	b. Provide appropriate information for production and service operations?				
	c. Contain or reference product acceptance criteria?				
	d. Define the characteristics of the product that are essential to its safe and proper use?				
	Are design and/or development output documents approved prior to release?				
	Documentation of design outputs is maintained and easily accessible?				
	A review of design outputs, change notices, customer complaints, and internal audit reports indicate consistent adherence to organizational standards for design output plans, etc.?				

7.3.4 Design and Development Review

	Are systematic reviews of design and/or development conducted at suitable stages?				
--	---	--	--	--	--

Do these reviews:

	a. evaluate the ability to fulfill requirements?				
--	--	--	--	--	--

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	b. identify problems and propose follow-up actions?				
	Do participants in such reviews include representatives of functions concerned with the design and/or development stage(s) being reviewed?				
	Are the results of the reviews and subsequent follow-up actions recorded?				
	At what stages of the design are plans or other design documented?				
	Where are records of design reviews maintained?				

7.3.5 Design and/or Development Verification

	Is design and/or development verification performed to ensure the output meets the design and/or development inputs?				
	Are the results of the verification and subsequent follow-up actions recorded?				

7.3.6 Design and/or Development Validation

	Is design and/or development validation performed to confirm that resulting product is capable of meeting the requirements for the intended use?				
	Wherever applicable, is validation completed prior to the delivery or implementation of the product?				
	If full validation is impractical prior to delivery or implementation, is partial validation performed to the extent applicable?				
	Are the results of the validation and subsequent follow-up actions recorded?				

7.3.7 Control of Design and Development Changes

	Are design and/or development changes identified, documented, and controlled?				
	Does this process include evaluation of the effect of the changes on constituent parts and delivered products?				

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	Are changes verified and validated, as appropriate, and approved before implementation?				
	Are the results of the review of changes and subsequent follow up actions documented?				

7.4.1 Purchasing Process

	Does the organization control its purchasing processes to ensure purchased product conforms to requirements?				
	Is the type and extent of control dependent upon the effect of subsequent realization processes and their output?				
	Does the organization evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements?				
	Are criteria for selection and periodic evaluation defined?				
	Are the results of evaluations and subsequent follow up actions recorded?				

7.4.2 Purchasing Information

	Do purchasing documents contain information describing the product to be purchased?				
--	---	--	--	--	--

Do these documents include where appropriate:

	a. requirements for approval or qualification of product, procedures, processes, equipment, and personnel?				
	b. quality management system requirements?				
	Is the adequacy of specified requirements contained in the purchasing documents reviewed prior to their release?				
	When purchasing good/services, does the purchaser provide subcontractors/suppliers with precise details of the order to ensure item/services are purchased correctly in the first place?				

NOTE: Sample purchase requisitions to determine the above.

7.4.3 Verification of Purchased Product

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	

	Have activities necessary for the verification of purchased product been identified and implemented?				
--	--	--	--	--	--

7.5.1 Control of Production and Service Provision

Does the organization control production and service operations through:

	a. the availability of information that specifies the characteristics of the product?				
	b. where necessary, the availability of work instructions?				
	c. the use and maintenance of suitable equipment for production and service operations?				
	d. the availability and use of measuring and monitoring devices?				
	e. the implementation of monitoring activities?				
	f. the implementation of defined processes for release, delivery, and applicable post-delivery activities?				

7.5.2 Validation of Processes for Production and Service Provision

	Does the organization validate any production and service processes where the resulting output cannot be verified by subsequent measurement or monitoring?				
	Are any processes included where deficiencies may become apparent only after the product is in use or the service has been delivered?				
	Does validation demonstrate the ability of the processes to achieve planned results?				

Do defined arrangements for validation include as applicable:

	a. approval/qualification of processes?				
	b. approval/qualification of equipment and personnel?				
	c. use of defined methodologies and procedures?				
	d. requirements for records?				

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	e. re-validation?				

7.5.3 Identification and traceability

	Is product identified by suitable means throughout production and service operations where appropriate?				
	Is the status of the product with respect to measurement and monitoring requirements clearly identified?				
	Where traceability is a requirement, is the unique identification of product controlled and recorded?				

7.5.4 Customer Property

	How does the organization exercise care with customer property while it is under the organization's control or being used by the organization?				
--	--	--	--	--	--

How is customer property provided for use or incorporation in product:

	a. Identified?				
	b. Verified?				
	c. Protected?				
	d. Maintained?				
	If any customer property is lost, damaged, or otherwise found to be unsuitable for use is it recorded and reported to the customer?				

7.5.5 Preservation of Product

	Is product preserved to ensure that conformity with customer requirements is maintained during internal processing and delivery to the intended destination?				
	Does this include identification, handling, packaging, storage, and protection?				
	Do these controls also apply to the constituent parts of a product?				

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	

7.6 Control of Measuring and Monitoring Devices

	How does the organization identify the measurements to be made and the measuring and monitoring devices required to assure conformity of product to specified requirements?				
	Are measuring and monitoring devices used and controlled to ensure that measurement capability is consistent with the measurement requirements?				

Where applicable, measuring and monitoring devices shall:

	a. be calibrated and adjusted periodically or prior to use, against devices traceable to International or national standards? a.1 Where no such standards exist, is the basis used for calibration recorded?				
	b. be safeguarded from adjustments that would invalidate the calibration?				
	c. be protected from damage and deterioration during handling, maintenance, and storage?				
	d. have the results of their calibration recorded?				
	e. have the validity of previous results reassessed if they are subsequently found out of calibration and corrective action taken?				

NOTE: Investigate methods in which measurement and monitoring devices are controlled to ensure fitness for use (i.e. identification of calibration status, traceability of device to calibration record, method in which frequency of calibration is determined).

	Is software used for measuring and monitoring of specified requirements validated prior to use?				
--	---	--	--	--	--

Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to:					
	a. demonstrate conformity of the product				
	b. ensure of the quality management system				

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	c. continually improve the effectiveness of the quality management system				

8.2.1 Customer Satisfaction

	Are measurement and monitoring activities needed to assure conformity and achieve improvement been identified and included in the product quality plan?				
	Does this process include the determination of the need for, and use of, applicable methodologies including statistical techniques?				

8.2.2 Internal Audit

	Are periodic internal quality audits conducted to determine whether the quality management system has been effectively implemented and maintained?				
	Are internal quality audits planned, including consideration of the status and importance of the activities and areas to be audited as well as the results of previous audits?				
	Is the audit scope, frequency, and methodologies defined?				
	Are audits conducted by personnel other than those who performed the activity being audited?				
	Are there documented procedures that include the responsibilities and requirements for conducting audits, ensuring their independence, recording results, and reporting to management?				
	Have personnel conducting internal audits been trained?				
	Are records of internal auditor training maintained and available?				
	Does management take timely corrective action on deficiencies found during the audit?				
	Do follow-up actions include the verification of the implementation of corrective action and the reporting of verification results?				

8.2.3 Measuring and Monitoring of Processes

	Are product realization processes measured and monitored by suitable methods to ensure customer requirements are met?				
--	---	--	--	--	--

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly affects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	

	Do these methods confirm the continuing ability of each process to satisfy its intended purpose?				
--	--	--	--	--	--

8.2.4 Measuring and Monitoring of Product (Service)

	Are product characteristics measured and monitored to verify that requirements for the product are met?				
	Is this carried out at appropriate stages of the product realization process?				
	Is evidence of conformity with the acceptance criteria documented?				

8.3 Control of Nonconformity

	Is product, which does not conform to requirements, clearly identified and controlled to prevent unintended use or delivery?				
	Are these activities defined in a documented procedure?				
	Does the organization deal with nonconforming product by one or more of the following: <ul style="list-style-type: none"> a. taking action to eliminate the nonconformity b. authorizing it's use, release or acceptance by relevant authority or when applicable by the customer c. taking action to preclude it's use or application 				
	Records of nonconformities and subsequent actions taken shall be developed and maintained.				
	Is nonconforming product corrected and subjected to re-verification after correction to demonstrate conformity?				
	When nonconforming product is detected after delivery or use has started, is appropriate action taken regarding the consequences of the nonconformity?				

8.4 Analysis of Data

	How is appropriate data collected and analyzed to determine the suitability and effectiveness of the quality management system and to identify improvements that can be made?				
--	---	--	--	--	--

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	

	Does this include data generated by measuring and monitoring activities and other relevant sources?				
--	---	--	--	--	--

How is this data analyzed to provide information on:

	a. customer satisfaction and/or dissatisfaction?				
	b. conformance to customer requirements?				
	c. characteristics of processes, product, and their trends?				
	d. suppliers?				

8.5.1 Continual Improvement

	Are processes necessary for the continual Improvement of the quality management system planned and managed?				
--	---	--	--	--	--

How is continual improvement of the quality management system facilitated through the use of:

	a. quality policy?				
	b. quality objectives?				
	c. audit results?				
	d. analysis of data?				
	e. corrective and preventive action ?				
	f. management review?				

8.5.2 Corrective Action

	How is corrective action taken to eliminate the cause of nonconformities in order to prevent recurrence?				
	Is corrective action appropriate to the impact of the Problems encountered?				

Is there a documented procedure for corrective action which defines requirements for:

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract

ISO 9001-2000 Audit Checklist

Ref Par	Requirement	Compliance Status			Comments
		COM	MIN	MJR	
	a. identifying nonconformities (including customer complaints)?				
	b. determining the causes of nonconformity?				
	c. evaluating the need for actions to ensure that nonconformities do not recur?				
	d. determining and implementing the corrective action needed?				
	e. recording results of action taken?				
	f. reviewing corrective action taken?				

8.5.3 Preventive Action

	Does the organization identify preventive action to eliminate the causes of potential nonconformities to prevent occurrence?				
	Are preventive actions taken appropriate to the impact of the potential problems?				

Is there a documented procedure for preventive action which defines requirements for:

	a. identifying potential nonconformities and their causes?				
	b. determining and ensuring the implementation of preventive action needed?				
	c. recording results of action taken?				
	d. reviewing preventive action taken?				
	Do the procedures ensure relevant information on actions taken is submitted for management review?				

COM - Compliance with requirement.

MIN - Minor noncompliance (administrative in nature). Requires a corrective action plan and estimated completion date prior to awarding a purchase order or subcontract.

MJR - Major noncompliance (directly effects the product). Requires corrective action implemented and validation prior to awarding a purchase order or subcontract