QMS documentation for a small company

ABC Company Inc.

ISO 9001:2000

Quality Management System Manual

Table of Contents

Document Revision Log

Revision Level	Revision Date	Section(s) Changed	Summary of Change(s)
0	04/01/2008	None	Initial release of document

1.0 Scope

ABC's quality management system (QMS) includes all ISO 9001 requirements except for:

1. Section 7.3, Design and Development

The justification for excluding this section is recorded in clause 7.3 of this Manual.

2.0 Company Profile

ABC Company Inc. began in 1995 as a manufacturer of specialty coatings for the ……. industry. From the beginning ABC has been the leader in …….

Product XXX which has set the standard in …… technology was introduced in country in ……. For the ……market as a …….application with …….capabilities. With this experience, ABC began the introduction of this technology to the world with projects executed in Europe/Eastern Europe, Asia, the Middle East and South America.

In 2000 ABC introduced the **Product YYYYY** as a truly unique innovation that provided a solution to the continuing problem of ……. **Product YYYY** has set new standards in …….for the protection of ……..

2.1 Responsibilities and Authority

Responsibilities and authorities of key personnel are described in section 5.5

2.3 Scope of Quality Management System Processes

ABC's QMS includes the following processes:

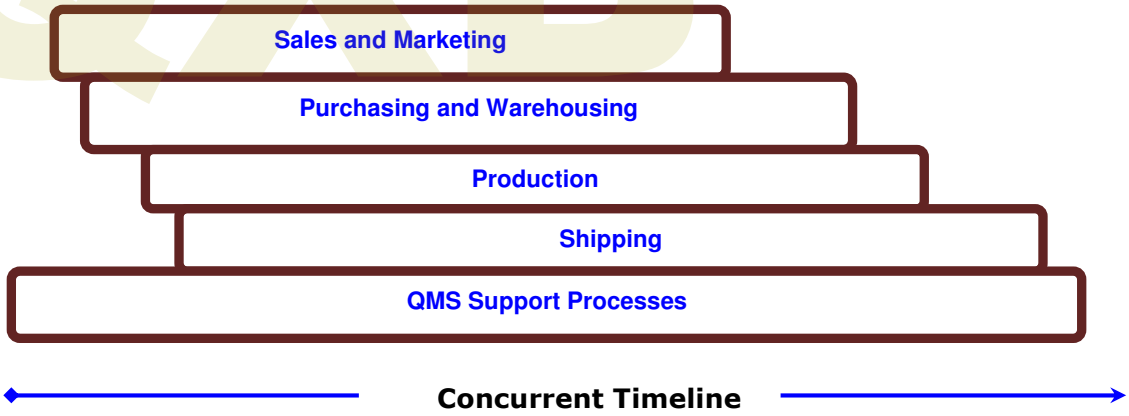
Business Processes:

1. Sales and marketing.
2. Production
3. Purchasing.
4. Warehouse processes – receiving, storage, packaging, shipping
5. Facility and equipment maintenance

QMS Processes:

6. Quality/product Planning
7. Management responsibilities – leadership, organization, quality policy and objectives, communication, customer satisfaction feedback, QMS review.
8. Document Control
9. Records Control
10. Customer Satisfaction
11. Corrective action and Preventive action
12. Control of non-conformances
13. Calibration

2.4 Business - Process Flow Map



2.5 Quality Policy (Change this to suit your organization)

We are committed to providing quality product and service to our customers and meeting all applicable ISO 9001:2000 requirements. We strive to continually improve our quality management system by reducing customer complaints, and improving on-time delivery and customer satisfaction.

3 Definitions & References

3.1 Definitions

We use terms and definitions as presented in ISO 9000: 2005

QMS stands for Quality Management System

Management Team: Is comprised of the two principal owners of the company. This team is responsible for managing the business and maintaining and continually improving the QMS

3.2 References

ISO9000: 2005 – Fundamentals and Vocabulary
ISO9001: 2000 – Requirements

4 Quality Management System

4.1 General Requirements

We have established, documented, implemented and maintains a QMS in accordance with the requirements of ISO9001:2000. We have identified our QMS processes (see paragraph 2.3 above); their sequence and interaction; the criteria and methods needed to ensure that both the operation and control of these processes are effective; ensured the availability of resources and information needed to support the QMS; we monitor measure and analyze these processes; and take action to achieve planned results and the continual improvement of our QMS. Any outsourced process or activity is controlled as per applicable ISO 9001 requirements.

4.2 Documentation Requirements

Our documentation includes a documented **Quality Policy** (paragraph 2.5 above) and quality objectives (for each process). Our **Quality Manual,** which includes procedures for the control of documents and records, internal audits, control of non-conformances,

corrective and preventive action and all necessary records to support our business and QMS. It identifies the scope of our QMS and provides details of and justification for any excluded ISO 9001 requirements. It also provides a description of the interaction of processes of the QMS.

4.2.3 Control of documents

We have a documented process (QP-01) to control all QMS documents described in section 4.2 that affect product, service and QMS conformity. The process includes controls to approve documents prior to issue; to review and update as necessary and re-approve document changes; a master list identifying changes and the current revision status of documents; to ensure that relevant versions of applicable documents are available at points of use; to ensure that documents remain legible and readily identifiable; to ensure that documents of external origin are identified and their distribution controlled; 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

We have a documented process (QP-02) to define controls to identify, store, protect, retrieve, retain and dispose of quality records. Records are legible, readily identifiable, retrievable and satisfy regulatory and customer requirements. We keep records (such as production records, product test data, and electronic data) to show evidence of conformity to requirements and effective operation of the QMS.

5 Management responsibility

5.1 Management commitment

We (management team- see Definitions) is committed to develop, implement and continually improve QMS effectiveness by: communicating to all employees, the importance of meeting product specifications and customer requirements, as well as statutory and regulatory requirements; establishing the QMS quality policy and objectives; conducting management reviews and ensuring the availability of resources.

5.2 Customer focus

We, along with our employees ensure that customer requirements are determined and met, with the aim of enhancing customer satisfaction through improving our QMS processes.

5.3 Quality Policy

We have developed a quality policy (see paragraph 2.5) that is appropriate for our company. It includes a commitment to comply with various requirements and to continually improve the QMS. It provides a framework for quality objectives, which are established for each process. We ensure that all employees are aware of and understand the policy. Finally, we review it for continuing suitability at business planning and management reviews.

5.4 Planning

5.4.1 Quality objectives

We have developed measurable quality objectives for both our products as well as our QMS processes. These objectives are set in our process documentation and tracked and reviewed monthly, as well as at management review meetings to ensure they are being achieved.

5.4.2 Quality management system planning

We have planned and documented our QMS through the Quality Manual; process flow procedures; product specifications; and quality forms, checklists and records related to each process. Collectively, these documents ensure that we meet our quality policy and QMS goals and objectives.

If we make any significant changes to our business, we ensure that the integrity of our QMS will not be disrupted.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

We ensure that employee duties, responsibilities and authorities are documented and communicated through job descriptions, processes and other documentation.

5.5.2 Management representative

Our Director of Operations is our Quality Management Representative. His QMS responsibilities include: ensuring that effective QMS processes are implemented and maintained; reporting to the management team on QMS performance and any need for improvement; and ensuring that all employees are aware of customer, QMS and regulatory requirements.

5.5.3 Internal communication

We ensure that we set up effective ways to communicate product, customer and regulatory requirements to all employees and also to provide them feedback on QMS performance and their role in making it effective.

5.6 Management review of the QMS

5.6.1 General

We review our overall QMS performance twice a year, to ensure its continuing suitability, adequacy and effectiveness. These reviews help us determine whether we need to make any improvements or changes to the QMS, our quality policy or objectives. Minutes are kept of all management reviews.

5.6.2 Review Input

Our QMS review agenda includes:

a) Results of internal and external audits,
b) Customer feedback - (annual surveys);
c) Process performance and product conformity - (to measurable objectives);
d) Status of preventive and corrective actions - (computer database);
e) Follow-up actions from previous management reviews (meeting minutes);
f) Changes that could affect the QMS – (meeting minutes);
g) Recommendations for improvement

5.6.3 Review output

We make sure that useful decisions and actions result from these reviews that relate to:

a) Improving the effectiveness of the QMS and its processes
b) Improving product related to customer requirements
c) Ensuring adequate resources for our business and QMS.

These decisions and actions are recorded in the minutes to each meeting

6 Resource management

6.1 Provision of resources

We plan for and provide adequate resources for our business and our QMS needs to ensure its continual effectiveness in enhancing customer satisfaction by meeting their requirements consistently. We accomplish this through our QMS and operational documentation.

6.2 Human Resources

We have set appropriate competency standards (based on education, training, skills and experience) to ensure that our employees are capable, in carrying out their duties and responsibilities effectively and efficiently. We also identify and provide specific training (where appropriate) for all personnel to ensure customer and QMS requirements are met.

We review all training given and our employee performance to ensure that employees are always aware of customer and quality requirements in the daily performance of their jobs. We maintain appropriate records for competency, as well any training given and its effectiveness.

6.3 Infrastructure

We plan for, provide and maintain adequate production and office facilities, production and test equipment, associated utilities, computers, and other resources necessary to achieve conformity to customer and QMS requirements.

6.4 Work environment

We control our work environment to ensure that we achieve product conformity, comply with regulatory requirements, and ensure the safety of our workforce.

7 Product Realization

7.1 Production Planning

We use product specifications and formulations to plan and manufacture our products, in accordance with our customer requirements and QMS controls. Our product planning includes quality objectives and production process steps for each product; material and equipment needed; documents and resources needed to ship the product; required verification, monitoring, inspection and test activities; product acceptance criteria; identification and traceability; records to show evidence that the shipments meet customer requirements.

The output of this planning is documented on work orders, forms, worksheets and related documentation.

7.2 Customer-related processes – Sales and Marketing

7.2.1 Determining Customer requirements

We identify and document all customer requirements, (stated or unstated), relevant to order fulfillment as well as, where known, statutory and regulatory requirements related to product shipment and any additional requirements determined by our company.

7.2.2 Review of Requirements

We review all contractual requirements whether in the form quotations, orders, contracts etc, **prior** to our commitment to supply product to the customer to ensure that:

1. The customer's product and delivery requirements are clearly specified and documented.
2. If the order or contract differs from our quotation, we resolve it prior to contract or order agreement.
3. We also check to ensure we have the capability to meet specified customer requirements.

We keep records of these reviews and any actions arising from them.

Where customer product or delivery requirements are changed, we ensure that affected documents are amended and that relevant personnel are made aware of the changed requirements.

We obtain customer authorization, in any situation where a formal review of contract requirements is not done.

7.2.3 Customer communication

We have effective methods for communicating with our customers regarding product information; enquiries, contracts, or order handling, including amendments, getting customer feedback or handling complaints.

7.3 Design and development

Product design and development is **not included** in the scope of our QMS, as this activity is conducted at our Head Office location.

7.4 Purchasing

7.4.1 Supplier Management

We have documented specifications for all purchased materials required for manufacturing our end product. We select, approve and control each of our suppliers that we purchase these materials from based on factors such criticality of the material, consistent quality and delivery, and their QMS status. These controls are documented in our purchasing process. We keep appropriate records of these activities.

7.4.2 Procurement

Our purchasing documents (PO's and contracts) clearly describe the materials needed, including any requirements related to delivery schedule, mode of delivery, shipment and test documentation, packaging, preservation, and other details as appropriate.

We review and approve all PO's and contracts, before transmission to the supplier.

7.4.3 Verification of purchased product

Where necessary or practical, we perform inspection and other activities to ensure that purchased materials meet our purchase requirements. In most cases we require certificates of assurance documentation for each shipment.

Where we, or our customers, intend to perform verification of materials at our supplier's premises, we specify the intended verification arrangements and method of product release, in our purchasing documents.

7.5 Production and service provision

7.5.1 Control of production and service provision

We have controls to plan and carry out our order fulfillment processes (sales, purchasing, production, supplier delivery logistics; customer delivery logistics) under controlled conditions that include, as applicable: providing employees with information that describes product and delivery characteristics (customer and supplier documentation; delivery documentation, worksheets, etc, as necessary); we use suitable production and test equipment; we have controls to monitor, measure and test product and ensure finished product quality prior to delivery.

7.5.2 Validation of Processes

The quality of all manufactured product is verifiable, so we do not need to use process validation controls.

7.5.3 Identification and Traceability

We use suitable means to identify raw materials, work in process and finished goods as well as their quality status through all stages of manufacture and delivery.

Where traceability is a requirement, we control and record the unique identification.

7.5.4 Customer Property

We exercise care (identify, store, maintain, protect) all customer property from receipt, storage, processing, packaging and shipment to final customer destination. If any customer property is lost, damaged or otherwise found to be unsuitable for use, we make and retain appropriate.

7.5.5 Preservation of product

We preserve all materials and finished product from receipt, through production and delivery to customers. Preservation controls include proper identification, handling, packaging, storage and protection.

7.6 Control of measuring and monitoring devices

We determine what needs to be monitored and measured and define the acceptance criteria; we identify the measuring devices to do it with; and we carry out monitoring and measurement activities to ensure conformity of product to requirements.

As appropriate, our measuring and monitoring devices are:

a) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, we record the basis used for calibration or verification;
b) Adjusted or readjusted as necessary,
c) Identified to determine their calibration status
d) Safeguarded from adjustments that would invalidate the measurement result,
e) Protected from damage and deterioration during handling, maintenance and storage;

Where a measuring device is found to be out of calibration, we check and record the validity of previous measuring results made with that device, with an alternate

calibrated measuring device. We take appropriate action on the defective device and any affected product and keep related records.

We do not use any computer software at this time for any monitoring or measuring activity.

8 Measurement, Analysis and Improvement

8.1 General

We have planned and implemented appropriate methods to monitor, measure, analyze and improve our processes in order to demonstrate product and delivery conformity and to continually improve the effectiveness of our QMS.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As a measure of QMS performance, we obtain feedback from customers as to whether we have met their requirements on each shipment as well as conduct an annual survey of overall customer satisfaction.

8.2.2 Internal audit

We conduct internal audits to determine whether our business activities have been effectively implemented and maintained in conformance with our QMS controls.

Our documented internal control procedure defines the responsibilities, planning, performance and reporting of results and maintenance of appropriate records.

All QMS processes are audited once a year and more frequent audits of some processes may take place based on the status and importance of the processes audited; the results of previous audits or where internal/external nonconformities or customer complaints occur.

The audit criteria, scope, frequency and use of audit methods are defined. We use an outside consultant to ensure objectivity and impartiality in the audit process.

The management team ensure that timely corrective actions are taken to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and reporting of verification results.

8.2.3 Monitoring and measurement of processes

We monitor and measure our QMS processes to demonstrate our ability to achieve planned results. When problems occur, we perform correction and corrective action, as appropriate, to ensure customer satisfaction.

8.2.4 Monitoring and measurement of product

We monitor and measure if product characteristics requirements have been met at appropriate stages of production, in accordance with our production plans.

We do not release finished product until all planned measuring and monitoring activities have been satisfactorily completed, unless otherwise approved by a manager and, where applicable, by the customer.

Products are not released until all verification activities are completed.

We maintain records to show evidence of conformity to acceptance criteria and the person(s) authorizing product release. Where products fail to pass any inspection or

test criteria, they are dealt with in accordance with the procedure on Control of nonconforming product.

8.3 Control of nonconforming product

We have a procedure to control nonconforming products. Our management team work with all parties involved to resolve issues. Resolution may involve taking action to eliminate the detected nonconformity; authorizing its use, release or acceptance under concession by our management team and where applicable, by the customer; return to the supplier; and by taking action to preclude its shipment.

We maintain records of the details of nonconformities and how they were resolved. If any nonconforming product is reworked, it is re-inspected to the specified requirements.

When nonconforming product is detected by the customer upon delivery, we take appropriate action to resolve it with the customer.

8.4 Analysis of data

We collect and analyze information from customer satisfaction surveys, supplier performance, product, production, QA and support and shipment activities, internal and external audits, etc, to continually improve the suitability and effectiveness of our QMS.

8.5 Improvement

8.5.1 Continual Improvement

We continually improve the effectiveness of our QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management reviews.

8.5.2 Corrective action

We have a procedure to take action on significant day to day problems (non-conformances) to eliminate the cause of nonconformities in order to prevent their recurrence. This may involve:

a) Reviewing nonconformities (including customer complaints and product returns)
b) Determining the causes of problems (nonconformities)
c) Evaluating and implement the appropriate actions to ensure that nonconformities do not recur
d) Keeping records of all actions and following up to ensure actions taken were effective.

8.5.3 Preventive action

At the QMS planning level, we review our product and process performance data, internal and external audit reports, customer satisfaction feedback, etc, to identify controls that may eliminate the cause of potential problems in order to prevent their occurrence. This may involve:

a) Reviewing potential nonconformities
b) Determining potential causes of problems (nonconformities)
c) Evaluating and implement the appropriate actions ensure that potential nonconformities do not occur
d) Keeping records of all actions and following up to ensure actions taken were effective.

Corrective and Preventive actions are appropriate to the effects of the actual or potential problems.

Change History

Revision Date:	Pages effected:	Details:	New Issue Number:
04/01/2007	Entire Manual	Original issue of the Quality Manual in compliance with the ISO 9001:2000 Standard	0

DISTRIBUTION
The Quality Manual is available as a controlled document on the Company hard drive as a read-only document. Printouts of the Quality Manual are discouraged and must be treated as uncontrolled by the reader.

QP 1 Control of Documents Procedure

1.0 Purpose
To define and establish the controls needed for documentation.

2.0 Scope
This procedure is applicable to documents used in the Quality Management System.

3.0 Related Documents
Document Master List

3.1 Responsibility
The Quality Management Representative (QMR) is responsible for all parts of this procedure.

4.0 Procedure
This procedure addresses the following controls:

4.1 Document Approval
Documents are approved for adequacy prior to their issue by the QMR. Approved documents are identified in the Quality Management System (QMS) folder on the C drive of the ABC computer system. The QMR approves documents for use by adding them to the Quality Management System folder. The review includes a check for accuracy, understandability, completeness and relevancy. Reviews are evidenced by the use of a manual or electronic signature/initials on all appropriate documentation by the QMR. The QMR also ensures that no documentation is issued without his review and approval.

4.2 Reviewing/Updating Documents
All documents are reviewed by the QMR on an annual basis for current consistency with existing practices. This review and any updates to specific documents are evidenced by the same approval method described above.

4.3 Document Change Control

Any employee may request a change to documents by marking up an existing copy and sending it to the QMR for review and change. The QMR reviews and approves/denies all requested changes. He verbally communicates changes to documents to the effected employees. When changes are made to the Quality Manual or procedures, the nature of the change is documented in the change history section of the document. When changes are made to forms, an obsolete electronic copy is retained for traceability.

4.4 Current Revisions

The QMR ensures that the current revisions of all internally developed documents are available on the C drive. He also maintains a Documents List, which identifies the document number and current effective date for each document, including electronic documents. All documents are identified with the revision number and effective date.

4.5 Document Availability

The QMR ensures the availability of current revisions of all documents to the operations to which they apply. Availability is evidenced through electronic and hard copy documents.

4.6 Document Legibility/Identification

Documents are presented in a legible fashion and are readily identifiable.

4.7 Externally Originated Documents

Externally originated documents used in the implementation of the QMS are clearly identified, and their distribution controlled the same way as internal documents.

4.8 Obsolete Documents

4.8.1 Obsolete Documents Removal

The QMR removes obsolete documents from the point of use and destroys them and only makes the latest version available to users.

4.8.2 Obsolete Documents Retention

When obsolete documents are retained for any purpose, the obsolete documents are clearly identified as "OBSOLETE ".

Change History

Revision Level	Revision Date	Section(s) Changed	Summary of Change(s)
0	04/01/2007	None	Initial release of document

QP 2 Control of Records

1 Purpose
To define and establish the controls needed for quality records.

2 Scope
This procedure is applicable to records used in the Quality Management System.

3 Related Documents
Records Master List

3.1 Responsibility
The QMR is responsible for managing this procedure. All employees are responsible for maintaining records in a legible fashion.

4.0 Procedure
This procedure addresses the following topics:

4.1 Establishment of Records
The QMR has established records to provide evidence of conformity to requirements and of the effective operation of the QMS. These records are identified in the Records Master List.

4.2 Legibility
All employees ensure that quality records are maintained in legible fashion.

4.3 Identification
The QMR identifies all quality records. Quality records are listed in the Records Master List.

4.4 Retrievability
Quality records are maintained in accessible areas and are readily retrievable by authorized personnel.

4.5 Storage
Hard copy records are filed in drawers, cabinets, boxes and binders. Some records are stored electronically.

4.6 Protection
Hard copy records are filed in drawers, cabinets, boxes and binders and are stored so as to prevent deterioration or loss. Electronic records are backed up each business day to prevent loss.

4.7 Retention Time
The minimum retention period for each quality record is identified on the Records Master List.

4.8 Disposition
The QMR can authorize the disposition of records in any of the following ways: Shredded; thrown in trash; deleted or archived.

4.9 Supplier/Customer Records

Some records of suppliers and customers are retained as quality records. These supplier/customer records are identified in the Records Master List

4.10 Electronic Records

Many quality records are maintained electronically. Electronic records are identified in the Records Master List.

4.11 Records List

The Records Master List identifies the document number, document title, retention responsibility, location kept, and minimum retention period for each quality record.

QUALITY RECORD	KEPT / STORED BY	HOW FILED	ACCESS	Retention Time
Business Plan	President	Secured Folder	All Managers.	3 years
Mgmt review	Quality	Binder by date	All Managers	2 years
Contract/Project Files	Engineering/Sales	Files by name/ project #	All Managers	7 years
Purchasing records	Purchasing	By Supplier	Purchasing	2 years
Lab Test Data	Lab	By product	Lab/Sales	7 years
Production records	Production	Product #	All Managers	3 years
Receiving/Shipping	Warehouse	Materials#/Supplier	All Managers	2 years
Calibration Records	Maintenance/Production	Binder and computer	All Managers	3 years
Internal Audit Reports	Quality	Binder - annually	All Managers	3 years
QMS Performance data	QMR	By Date	All Managers	2 years

4.12 Change History

Revision Level	Revision Date	Section(s) Changed	Summary of Change(s)
0	01/10/2007	None	Initial release of document

QP 3 Internal Audit Procedure

1 Purpose

To define and establish the controls needed for internal audits

2 Scope

This procedure is applicable to internal audits of the Quality Management System.

3. Related Documents

Audit Schedule
Process Audit Form
Corrective Action
Audit Report

4.0 Procedure

4.1 Internal Auditor Qualification

All internal audits for ABC are conducted by an external ISO 9001 Consultant. This ensures competence, objectivity and impartiality in the audit process

4.2 Audit Scheduling

The QMR in conjunction with the Consultant schedules internal audits on an annual basis. The frequency with which specific processes and ISO 9001elements of the QMS are scheduled is determined taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The full QMS is planned to be audited prior to the Registrar's audit.

4.3 Audit Execution

The Consultant uses a process-based checklist to document all findings.

4.4 Audit Reporting

The Consultant writes an Audit Report for each audit performed. The Audit Report is given to the QMR and is used as an input for the management review meeting.

4.5 Corrective/Preventive Action

The Audit Report details all nonconformities identified during the audit for which corrective action is required as well as any opportunities for improvement. The QMR ensures that all corrective action is taken, to effectively close out the nonconformities identified.

Corrective actions and preventive actions are documented as per Corrective Action, QP05. All audit reports are kept on file and serve as input for the management review process.

Audit results of all QMS processes are reviewed at each Management Review meeting.

4.6 Change History

Revision Level	Revision Date	Section(s) Changed	Summary of Change(s)
0	04/01/07	None	Initial release of document

QP4 – Control of Nonconforming Service

1. Purpose

To define and establish the controls needed to ensure that nonconforming product is prevented from unintended use or delivery, where practical.

2. Scope

This procedure is applicable to controlling nonconforming product, process and delivery. Systemic nonconformities are addressed through Internal Audits, QP03.

3. Related Documents

Internal Audits, QP03
Corrective Action, QP05
Nonconformance database
Hold Tag

3.1 Responsibility

The QMR or delegate is responsible for all requirements of this procedure.

4.0 Procedure

This procedure addresses the following topics:

4.1 Identification and Segregation

Any employee may identify a nonconformance and notify a manager or QMR. The QMR or delegate will attach a Hold or Reject tag on the nonconforming product or material and record it in the Nonconformance database. The item may be segregated in a designated area if practical, or clearly indicate it is not to be further processed, unless authorized by a manager.

4.2 Evaluation and Disposition

The QMR or delegate evaluates what actions are needed to resolve the nonconformance and documents it on the Hold tag. He may consult any employee or other manager in determining the appropriate course of action. Once the disposition action is taken, the nonconformance is closed off and the Hold Tag is and NCR database is updated.

If the action is to rework the nonconforming product, the QMR ensures that it is re-inspected and appropriate inspection records are kept, before closing off the Hold Tag and updating the NCR database.

A summary of nonconformance activities are presented and discussed at each Management Review meeting.

QMS Control	Type of non-conformance						
	Receiving	Warehouse	Production	Shipping	Supplier	In-Field	Customer
Identify	Any personnel						
Notify							
Record in database							
Segregate							
Evaluate							
Disposition							
Close out in database							
Review Database	Quality Manager						

Change History

Revision Level	Revision Date	Section(s) Changed	Summary of Change(s)
0	04/01/2007	None	Initial release of document

QP 5 Corrective & Preventive Action

1.0 Purpose

To describe the controls needed taking corrective and preventive actions, in order to eliminate the cause of actual or potential nonconformities.

2.0 Scope

This procedure is applicable to corrective/preventive actions related to nonconforming services and audit results.

3.0 Related Documents

CAR Form
CAR database

4.0 Procedure

This procedure addresses the following topics:

4.1 General Requirements

We take action to eliminate the causes of all significant actual or potential nonconformities in order to prevent occurrence or recurrence.
Corrective/preventive actions are appropriate to the effects of the actual or potential nonconformity.

4.2 Review of Non-conformances

The QMR or delegate reviews operational data and nonconformities, including customer complaints, on a regular basis. Performance data, external and internal audit results and customer satisfaction feedback are also reviewed at management reviews and periodic management team meetings. The CAR form is used to record the details of each corrective/preventive action and track its progress and close out. The CAR database is used to summarize and track timely close out of all CA's or PA's.

4.3 Cause Investigation

The QMR or delegate investigate the (actual or potential) cause(s) of the nonconformity and documents it on the CAR form or claims worksheet. The root cause(s) of any nonconformance may be determined through discussions with employees, review of quality records and repeating process steps.

4.4 Evaluation of Need for Corrective/preventive Action

Based on the results of Cause Investigation, the QMR or delegate determines the corrective/preventive action that needs to be taken and implements it.

4.5 Records of Results

The QMR or delegate completes all relevant sections of the CAR/PAR Form and the QMR follows up each CAR/PAR to ensure that the actions were effective in eliminating the root cause. The QMR signs off each CAR/PAR to indicate this and updates the CAR/PAR database.

A summary of CAR/PAR activities is presented and discussed at each Management Review meeting.

Document Change History

Revision Level	Revision Date	Section(s) Changed	Summary of Change(s)
0	04/01/2007	None	Initial release of document