The following is an example systems manual from a low volume (TE, but not an automotive supplier) company.

You will note that this is essentially a copy of ISO 9001:2000. I take this path because long ago I got tired of an auditor picking a phrase or line item out of the standard and ask where that item was addressed. Sometimes it was from a laundry list type of situation. The bottom line is they would mumble about the "…words aren't there…". An example is traceability. Many companies do no traceability – no need. But – you still have to address the issue by saying you recognize and understand the requirement and that your company sees no need for traceability.

Consider the following from the 1994 version:

4.5.2 Document and data approval and issue

The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;
b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

In one audit the auditor did a minor writeup because although line item 'c' was addressed (the system did this) but nowhere were the words: "…any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified…"

So – why get into a pissing match?

Technically your quality manual may be a statement of scope, exclusions statement, and a cross-reference matrix. Line item 'c' seems to imply you will have a high level systems flow chart as well. In the flow charts powerpoint file you will see this type of high level systems flow chart. Typical Top Level Operations Flowchart is one example style. Main Processes / Systems is another style. Both of these are in **Flow_Charts_for_2000.ppt**. In addition, you will find help with understanding how to do yours in the main powerpoint file Implementation-A Beta3.ppt (the revision may change [A Beta3], but you get the idea. Look in the section titled A Quality Management System? Near the front of the file. Note that I can't cite pages as the file is evolving so if I cite one here now and forget to change it here after a change to the other file I'll be misleading you.

When you consider this high level flow chart, consider your business as a whole – this is where process mapping comes into play as well.

The following is the 2000 quality (systems) manual requirement:

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the **scope of the quality management system**, including **details of and justification for any exclusions** (see 1.2),
b) the documented procedures established for the quality management system, **or reference to them**, and
c) a **description of the interaction between the processes of the quality management system**.

Since 1993 I have been implementing in this manner with no problems, but you have to decide how you want to address the issue of the contents of your quality manual. Just remember – the words of every line item have to be addressed even if you do not do it for whatever reason.

This company chose not to number documents. Instead they simply referenced the titles of the documents. Where you see something like:

> Supporting Documentation
> ***Quality Records Map***

That is their document identification system. From this, you can see that how you identify your documents is entirely up to you and will in large part depend upon the size and complexity of your company, its processes and systems complexity. Typically complex numbering or naming systems in small companies are not necessary and, in fact, are somewhat silly. I prefer the document file name, personally, rather that a title, but hey – what the heck, right?

The included file Doc_Review_Tracking.xls is an example of a company which identified documents by their title. In Document_Matrix_Example.xls you will find an example where a company used the disk file name of documents for identification.

Don't get caught up in complex identification schemes! Do what is appropriate for your company!

A last thing to remember is **you cannot complete this manual until your systems are all mapped**. You may project what your level II's will be and such, but believe me. The systems manual is the last document to 'go golden'.

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ISO9001:2000
Quality Systems Manual

Company X, Inc.

Revision 1/31/02

Table of Contents

1.0 Scope

This Quality Manual provides specifics on the policies and procedures used by Company X, Inc. and Company X Consumer Products, Inc. to meet ISO9001 Quality Management System requirements.

Company X, Inc. has no permissible exclusions as they apply to the organization or its products under the ISO9001 requirements.

Company X Consumer Products, Inc. has excluded section 7.3 Design and Development from the applicable requirements of ISO9001, due to the nature of the organization and its products. This exclusion does not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

2.0 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of ISO9001. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on ISO9001 are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies.

ISO9000 Quality Management System –Fundamentals and Vocabulary.

3.0 Terms and definitions

The term "organization" used in this quality manual refers to Company X, Inc. and Company X Consumer Products.
"Supplier" and "Vendor" are synonymous and refer to the external source used to acquire purchased products and/or services by the organization.
Throughout the text of this Quality Manual wherever the term "product" occurs, it can also mean "service".

4.0 Quality management system

4.1 General requirements

The organization documents, implements and maintains a quality management system and continually improves its effectiveness in accordance with the requirements of the ISO9001 International Standard.

The organization:

a) identifies the processes needed for the quality management system and their application throughout the organization,
b) determines the sequence and interaction of these processes,
c) determines criteria and methods needed to ensure that both the operation and control of these processes are effective,
d) ensures the availability of resources and information necessary to support the operation and monitoring of these processes,
e) monitors, measures and analyzes these processes, and
f) implements actions necessary to achieve planned results and continual improvement of these processes.

These processes are managed by the organization in accordance with the requirements of the ISO9001 International Standard. Where the organization chooses to outsource any process that affects product conformity with requirements, the organization ensures control over such processes. Control of such outsourced processes are identified within the quality management system.

NOTE: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization and measurement.

4.2 Documentation requirements

4.2.1 General

The quality management system documentation includes:

a) documented statements of a quality policy and quality objectives,
b) a quality manual,
c) documented procedures required by the ISO9001 International Standard,
d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and
e) records required by the ISO9001 International Standard.

NOTE 1: Where the term " documented procedure" appears within the ISO9001 International Standard, means that a procedure is established, documented, implemented and maintained.

NOTE 2: Documentation can be in any form or type of medium.

4.2.2 Quality manual

The organization establishes and maintains a quality manual that includes
a) the scope of the quality management system, including details of and justification for any exclusions,
b) the documented procedures established for the quality management system, or reference to them, and
c) a description of the interaction between the processes of the quality management system.

Supporting Documentation
Quality System Overview Map

4.2.3 Control of documents

Documents required by the quality management system are controlled. Records required by the quality management system are controlled according to the requirements given in 4.2.4. A documented procedure is established to define the controls needed:
a) to approve documents for adequacy prior to issue,
b) to review and update as necessary and re-approve documents,
c) to ensure that changes and the current revision status of documents are identified,
d) to ensure that relevant versions of applicable documents are available at points of use,
e) to ensure that documents remain legible and readily identifiable,
f) to ensure that documents of external origin are identified and their distribution controlled, and
g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Supporting Documentation
Document Control Map
Controlled Documents of External Origin Map

4.2.4 Control of records

Records are established and maintained to provide evidence of conformity to requirements and or the effective operation of the quality management system. Records remain legible, readily identifiable and retrievable. A documented procedure is established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Supporting Documentation
Quality Records Map

5.0 Management responsibility

5.1 Management commitment

Top management is committed to the development and implementation of the quality management system and continually improves its effectiveness by:
a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing a quality policy,
c) establishing quality objectives,
d) conducting management reviews, and
e) ensuring the availability of resources.

5.2 Customer focus

Top management ensures 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

'We are committed to consistently meet or exceed our customers' expectations in product performance, service, and delivery. We promote continuous improvement of customer satisfaction by maintaining and reviewing an ISO9001 quality system."

Top management ensures that the quality policy

a) is appropriate to the purpose of the quality policy,
b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
c) provides a framework for establishing and reviewing quality objectives,
d) is communicated and understood within the organization, and
e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management ensures that quality objectives, including those needed to meet requirements for product [see 7.1 a], are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy.

1. Meet or exceed customer expectations by effective communication and review of customer requirements.
2. Provide our customers high quality products and services, on time delivery, and at a reasonable cost.
3. Effectively manage our products, processes, and services to provide superior customer satisfaction.
4. Promote the safety, awareness, and well being of employees through training and education.

5.4.2 Quality management system planning

Top management ensures that:

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
b) 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

Top management ensures that responsibilities and authorities are defined and communicated within the organization to promote effective management of the quality system. A Management Hierarchy Map illustrates the responsibility and relative authority of the personnel who manage, perform, and verify the activities affecting the QMS. A Steering Committee has been appointed to evaluate and implement requirements of, as

well as improvements to, the ISO9001 Quality Management System. The Steering Committee is made up of representing members from departments within the organization.

Supporting Documentation
Management Hierarchy Map

5.5.2 Management representative

Top management has appointed a management representative who, irrespective of other responsibilities, has the responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,
b) reporting to top management on the performance of the quality management system and any need for improvement, and
c) ensuring the promotion of awareness of customer requirements throughout the organization.

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

Top management ensures 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

Top management reviews the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. The review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews are maintained (see 4.2.4).

Supporting Documentation
Management Review Map

5.6.2 Review input

The input to management review includes information on:

a) results of audits,
b) customer feedback,
c) process performance and product conformity,
d) status of preventive and corrective actions,
e) follow-up actions from previous management reviews,
f) changes that could affect the quality management system, and
g) recommendations for improvement.

5.6.3 Review output

The output from the management review includes any decisions and actions related to:

a) improvement of the effectiveness of the quality management system and its processes,
b) improvement of product related to customer requirements, and
c) resource needs.

6.0 Resource management

6.1 Provision of resources

The organization determines and provides the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and
b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

The organization :

a) determines the necessary competence for personnel performing work affecting product quality,
b) provides training or takes other actions to satisfy these needs,
c) evaluates the effectiveness of the actions taken,
d) ensures that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
e) maintains appropriate records of education, training, skills and experience (see 4.2.4).

Supporting Documentation
Training Map

6.3 Infrastructure

The organization determines, provides for, and maintains 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

The organization determines and manages the work environment needed to achieve conformity to product requirements.

7.0 Product realization

7.1 Planning of product realization

The organization plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system (see 4.1). In planning product realization, the organization determines the following, as appropriate:

a) quality objectives and requirements for the product,
b) the need to establish processes, documents, and provide resources specific to the product,
c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance, and
d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of the planning is in a form suitable for the organizations method of operations.

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, is referred to as the quality plan.

NOTE 2 The organization also applies the requirements given in 7.3 to the development of product realization processes.

Supporting Documentation
Production Development Map

7.2 Customer- related processes

7.2.1 Determination of requirements related to the product

The organization determines:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,
c) statutory and regulatory requirements related to the product, and
d) any additional requirements determined by the organization.

Supporting Documentation
Sales Quote Map
Order Entry Map
Order Change Map
Technical Service Map

7.2.2 Review of requirements related to the product

The organization reviews the requirements related to the product. This review is conducted prior to the organizations 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 ensures that:

a) product requirements are defined,
b) contract or order requirements differing from those previously expressed are resolved, and
c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review are maintained (see 4.2.4). Where the customer provides no documented statement of requirement, the customer requirements are confirmed by the organization before acceptance. Where product requirements are changed, the organization ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

Supporting Documentation
Special Order Traveler Map
Sales Quote Map
Order Entry Map
Order Change Map

7.2.3 Customer communication

The organization determines and implements effective arrangements for communicating with customers in relation to:

a) product information,
b) enquiries, contracts or order handling, including amendments, and
c) customer feedback, including customer complaints.

Supporting Documentation
Customer Complaints Map
Sales Quote Map
Order Entry Map
Order Change Map

7.3 Design and development

7.3.1 Design and development planning

The organization plans and controls the design and development of product. During the design and development planning, the organization determines:

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and
c) the responsibilities and authorities for design and development.

The organization manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility. Planning output is updated, as appropriate, as the design and development progresses.

Supporting Documentation
Design Control Map

7.3.2 Design and development inputs

Inputs relating to product requirements are determined and records maintained (see 4.2.4). These inputs include:

a) functional and performance requirements,
b) applicable statutory and regulatory requirements,
c) where applicable, information derived from previous similar designs, and
d) other requirements essential for design and development.

These inputs are reviewed for adequacy. Requirements are complete, unambiguous and do not conflict with each other.

Supporting Documentation
Design Control Map
Special Order Traveler Map

7.3.3 Design and development outputs

The outputs of design and development are provided in a form that enables verification against the design and development input and are approved prior to release. Design and development outputs:

a) meet the input requirements for design and development,
b) provide appropriate information for purchasing, production and for service provision,
c) contain or reference product acceptance criteria, and
d) specify the characteristics of the product that are essential for its safe and proper use.

Supporting Documentation
Design Control Map
Part Number Request Map
Special Order Traveler Map
Product Manual Request Map
Software Control Map

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development are performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and
b) to identify any problems and propose necessary actions.

Participants in such reviews include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions are maintained (see 4.2.4).

Supporting Documentation
Design Control Map

7.3.5 Design and development verification

Verification is 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. Records of the results of the verification and any necessary actions are maintained (see 4.2.4).

Supporting Documentation
Design Control Map

7.3.6 Design and development validation

Design and development validation is 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. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions is maintained (see 4.2.4).

Supporting Documentation
Laboratory Request Map

7.3.7 Control of design and development changes

Design and development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions are maintained (see 4.2.4).

Supporting Documentation
Engineering Change Request Map
Technical Bulletin Request Map

7.4 Purchasing

7.4.1 Purchasing process

The organization ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization evaluates and selects suppliers based on their ability to supply product in accordance with the organizations requirements. Criteria for selection, evaluation and re-evaluation is established. Records of the results of evaluations and any necessary actions arising from the evaluation is maintained (see 4.2.4).

Supporting Documentation
Purchasing Control Map
Supplier Approval Map

7.4.2 Purchasing Information

Purchasing information describes the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,
b) requirements for qualification of personnel, and
c) quality management system requirements.

The organization ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3. Verification of purchased product

The organization establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the organization or its customer intends to perform verification at the supplier's premises, the organization states the intended verification arrangements and method of product release in the purchasing information.

Supporting Documentation
Product Receiving Map
Quality Control Map

7.5 Production and service provision

7.5.1 Control of production and service provision

As applicable, the organization plans and carries out production and service provisions under controlled conditions. Controlled conditions include:

a) the availability of information that describes the characteristics of the product,
b) the availability of work instructions, as necessary,
c) the use of suitable equipment,
d) the availability and use of monitoring and measuring devices,
e) the implementation of monitoring and measurement activities, and
f) the implementation of product release, delivery and post-delivery activities.

Supporting Documentation
Production Control Map
Process Control Map
Delivery Map
Equipment Maintenance Map
Nonconformance Control Map
Quality Control Map
Product Identification Map
Product Handling and Storage Map
Technical Service Map

7.5.2 Validation of processes for production and service provision

The organization validates any processes for production and service provisions 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 in use or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results. As applicable, the organization establishes arrangements for these processes including:

a) defined criteria for review and approval of the processes,
b) approval of equipment and qualification of personnel,
c) use of specific methods and procedures,
d) requirements for records (see 4.2.4), and
e) revalidation.

7.5.3 Identification and traceability

Where appropriate, the organization identifies the product by suitable means throughout product realization. The organization identifies the product status with respect to monitoring and measurement requirements. Where traceability is a requirement, the organization controls and records the unique identification of the product (4.2.4).

Supporting Documentation
Quality Control Map
Delivery Map

7.5.4 Customer property

The organization exercises care with customer property while it is under the organizations control or being used by the organization. The organization identifies, verifies, protects and safeguards customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, it's reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property.

Supporting Documentation
Returns and Repairs Map
Customer Supplied Product

7.5.5 Preservation of product

The organization preserves the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling,

packaging, storage and protection. Preservation also applies to the constituent parts of a product.

Supporting Documentation
Product Handling and Storage Map
Product Identification Map

7.6 Control of monitoring and measuring devices

The organization determines 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). The organization establishes processes to ensure that monitoring and measurement can be carried out, and is carried out in a manner that is consistent with the monitoring and measurement requirements. Where necessary to ensure valid results measuring equipment is:

a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded,
b) adjusted or re-adjusted as necessary,
c) identified to enable the calibration status to be determined,
d) safeguarded from adjustments that would invalidate the measurement result, and
e) protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification is maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This is undertaken prior to initial use and reconfirmed as necessary.

Supporting Documentation
Calibration Map

8.0 Measurement, analysis and improvement

8.1 General

The organization plans and implements the monitoring, measurement, analysis and improvement processes needed:

a) to demonstrate conformity of the product,
b) to ensure conformity of the quality management system, and
c) to continually improve the effectiveness of the quality management system.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

Supporting Documentation
Statistical Techniques Map

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization monitors information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information is determined.

Supporting Documentation
Customer Complaints Map

8.2.2 Internal Audits

The organization conducts internal audits at planned intervals to determine whether the quality management system:

a) conforms to the planned arrangements (see 7.1), to the requirements of ISO9001 and to the quality management system requirements established by the organization, and
b) is effectively implemented and maintained.

An audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined. Selection of auditors and conduct of audits ensure objectivity and impartiality of the audit process. Auditors do not audit their own work. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) is defined in a documented procedure.

The management responsible for the area being audited ensures that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results (see 8.5.2).

Supporting Documentation
Internal Audits Map

8.2.3 Monitoring and measurement of processes

The organization applies suitable methods for monitoring and where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product.

8.2.4 Monitoring and measurement of product

The organization monitors and measures the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of product (see 4.2.4). Product release and service delivery does 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.

Supporting Documentation
Quality Control Map

8.3 Control of nonconforming product

The organization ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming products are defined in a documented procedure. The organization deals with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity,
b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer, and
c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, are maintained (see 4.2.4). When nonconforming product is corrected the product is subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the organization takes action appropriate to the effects, or potential effects, of the nonconformity.

Supporting Documentation

Nonconformance Control Map

8.4 Analysis of data

The organization determines, collects and analyzes 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. This includes data generated as a result of monitoring and measurement and from other relevant sources. The analysis of data provides information relating to:

a) customer satisfaction (see 8.2.1),
b) conformity to product requirements (see 7.2.1),
c) characteristics and trends of processes and products including opportunities for preventive action, and suppliers.

Supporting Documentation
Customer Complaints Map
Internal Audits Map
Corrective Action Map
Preventive Action Map
Nonconformance Control Map

8.5 Improvement

8.5.1 Continual improvement

The organization continually improves 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 reviews.

8.5.2 Corrective action

The organization takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered. A documented procedure is established to define requirements for:

a) reviewing nonconformities (including customer complaints),
b) determining the causes of nonconformities,
c) evaluating the need for action to ensure that nonconformities do not recur,
d) determining and implementing action needed,
e) records of the results of action taken (see 4.2.4), and
f) reviewing corrective action taken.

Supporting Documentation
Corrective Action Map

8.5.3 Preventive action

The organization determines actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems. A documented procedure is established to define requirements for:

a) determining potential nonconformities and their causes,
b) evaluating the need for action to prevent occurrence of nonconformities,
c) determining and implementing action needed,
d) records of results of action taken (see 4.2.4), and
e) reviewing preventive action taken.

Supporting Documentation
Preventive Action Map