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## PERMISSIBLE EXCLUSIONS (ISO 9001:2008)

| Description | Section No. |
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## ORGANISATION PROFILE

Aran Services are dedicated to providing householders with cost effective energy efficiency solutions that not only reduce household running costs, but limit the impact that you and your family have on the environment by cutting down your carbon dioxide emissions.

Operating from purpose-built premises in the centre of the Eastern Region, the company offers a 'Whole House' solution to the energy efficiency challenge, based on the understanding that every element of a building's energy consumption should be considered in order to increase its overall energy efficiency and reduce its carbon footprint.

Since our formation in 2004, Aran Services Ltd has striven to provide its customers and clients in both public and private sectors with excellence in the field of energy efficiency.

At Aran Services Ltd our skilled workforce of installers, surveyors and managerial staff are focussed on providing an exceptional customer service, employing a range of services from initial energy assessment through to the installation of renewable energy technologies in order to provide our clients with the best possible energy efficiency solution. We pride ourselves on our professionalism, a fact reflected by our membership of the appropriate trade bodies and our commitment to continuous staff training.

We continue to work closely with government bodies and energy suppliers to ensure access for our clients to the various and evolving grant funding streams that can reduce the cost of energy efficiency.

## ORGANISATION FOREWORD

This Quality Assurance Manual is the means by which Aran Services Ltd (hereinafter referred to as the 'Organisation') satisfies the requirements of its customers, particularly with regard to management responsibility.

The Organisation is obliged to ensure that its Quality Policy is understood by its employees, and that its procedures are implemented and maintained at all times. This Quality Assurance Manual is in accordance with the requirements of ISO 9001:2008. The quality system shall be periodically and systematically reviewed by management and checked by quality audits both internal and external.

The Quality Manager is responsible for the control of all matters pertaining to the implementation of procedures and quality matters.

The assurance of quality is fundamental to all the work undertaken by the Organisation and all personnel, at every level in the Organisation's structure, shall practice the procedures established.



## QUALITY POLICY

The primary purpose of quality assurance is the enhancement of the quality of customer experience and the maintenance of installation standards in the context of an expanding portfolio of service streams.

The continuing policy of Aran Services Ltd is to provide a professional and efficient service to meet all of the requirements of our customers. This achievement will result in securing efficiency and enhancement of long-term profitability.

The Management Team bears the responsibility for establishing, maintaining and implementing the system for controlling those particular activities for which they are responsible. We undertake to ensure through instruction, practical example and training that quality is the aim of all members of the Organisation and that each employee has a proper understanding of the importance of the quality system function and its direct relevance to the success of the Organisation.

All staffs are expected to take personal responsibility for their own professional quality and standards in all their activities.

Staff will exercise this responsibility within a supportive environment where expectations and standards are defined, continual improvement and innovation are encouraged, development and training opportunities are provided, feedback is actively sought from customers and other major stakeholders; and duplication of effort is strenuously avoided.

The quality assurance framework:

- Sets objectives rather than dictates detailed procedures and structures;
- Promotes consistency rather than standardisation across the company and
- Is underpinned by the concepts of equality and fairness

All policies and procedures will be documented and readily accessible to staff, students and other stakeholders.

The Company will rigorously and continuously monitor the effectiveness of its quality assurance procedures to assure that they are operating in accordance with good practice, in the best interests of customers and the maintenance of installation standards and the promotion of continual improvement through:

*Quality Assurance* comprises all the policies, systems and processes directed to ensuring the enhancement of the quality and standards of service provision.

*Quality Control* relates to the arrangements (procedures, organisation etc.) which verify that installation, training and assessment are being carried out in an appropriate manner.

*Quality Audit* is the process of ensuring that the quality assurance and control arrangements are satisfactory and operating effectively.

*Quality Enhancement* is the process of continual improvement.

The organisation has a policy of continual improvement and setting of quality objectives in line with the framework laid down within ISO 9001:2008.

The Quality System will be monitored regularly under the Top Management’s ultimate responsibility with regular reporting of the status and effectiveness at all levels.

Signed .....

Date .....

## SCOPE OF CERTIFICATION

This Quality Manual covers the products and services offered by Aran Services Ltd included in the scope definition below:

### **Energy Efficiency “Whole House” Solutions**

The Management System is designed to meet the requirements of:

### **ISO 9001:2008**

Certification covers activities at the site address specified on the cover sheet of this manual and associated operations.

## 5.5 Responsibility, Authority & Communication

### ORGANISATION CHART

## 5.5 Responsibility, Authority & Communication - Continued

| Quality Responsibility |   | Name           |
|------------------------|---|----------------|
| 4.1                    | Quality Management System Requirements  | Top Management |
| 4.2                    | Documentation Requirements  |                |
| 5.1                    | Management Commitment   |                |
| 5.2                    | Customer Focus  |                |
| 5.3                    | Quality Policy  |                |
| 5.4                    | Quality Management System Planning / Objectives   |                |
| 5.5                    | Responsibility, Authority & Communication   |                |
| 5.6                    | Management Review   |                |
| 6.1                    | Provision of Resources  |                |
| 6.2                    | Human Resources, Competence, Awareness & Training   |                |
| 6.3                    | Infrastructure  |                |
| 6.4                    | Work Environment  |                |
| 7.1                    | Planning of Product Realisation   |                |
| 7.2                    | Customer Related Processes, Determination & Review of Requirements, Customer Communication                          |                |
| 7.3                    | Design & Development Planning, Inputs, Outputs, Review, Verification, Validation & Changes Control                  |                |
| 7.4                    | Purchasing Process, Information & Verification  |                |
| 7.5                    | Production & Service Provision, Control, Validation, Identification, Traceability, Preservation & Customer Property |                |
| 7.6                    | Control of Monitoring & Measurement Devices   |                |
| 8.1                    | Measurement, Analysis & Improvement   |                |
| 8.2                    | Monitoring & Measurement of Processes & Product, Internal Audits, Customer Satisfaction                             |                |
| 8.3                    | Control of Non Conforming Product   |                |
| 8.4                    | Analysis of Data  |                |
| 8.5                    | Continual Improvement, Corrective Action, Preventive Action   |                |

## 4 QUALITY MANAGEMENT SYSTEM

### 4.1 GENERAL REQUIREMENTS

The Organisation shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The Organisation shall:

- a) Determine the processes needed for the quality management system and their application throughout the Organisation.
- b) Determine the sequence and interaction of these processes.
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective.
- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.
- e) Monitor, measure (where applicable) and analyse these processes.
- f) Implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the Organisation in accordance with the requirements of this International Standard.

Where an Organisation chooses to outsource any process that affects product conformity to requirements, the Organisation shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1: Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realisation and measurement, analysis and improvement.

NOTE 2: An outsourced process is identified as one being needed for the organisation's quality management system, but chosen to be performed by a party external to the organisation.

NOTE 3: Ensuring control over outsourced processes does not absolve the organisation of the responsibility of conformity to all Customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

- a) The potential impact of the outsourced process on the organisation's capability to provide product that conforms to requirements.
- b) The degree to which the control for the process is shared.
- c) The capability of achieving the necessary control through the application of clause 7.4.

### 4.1

*The management have established and implemented a documented system which is aimed at continual improvement. They have identified their processes, interactions and criteria for operational control and monitoring of the processes.*

*Management will ensure adequate resources are available. Any outsourced processes will be covered within appropriate procedures in order that effective control is ensured.*

## 4.2 DOCUMENTATION REQUIREMENTS

### 4.2.1 General

The quality management system documentation shall include:

- a) Documented statements of a quality policy and quality objectives.
- b) A quality manual.
- c) Documented procedures and records required by this International Standard.
- d) Documents including records determined by the Organisation to be necessary to ensure the effective planning, operation and control of its processes.

NOTE 1: Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may include the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2: The extent of the quality management system documentation can differ from one Organisation to another due to:

- a) The size of Organisation and type of activities.
- b) The complexity of processes and their interactions.
- c) The competence of personnel.

NOTE 3: The documentation can be in any form or type of medium.

### 4.2.1

*Management have defined the Organisation’s quality policy and continually set objectives.*

*A quality manual and procedures manual are in place. This covers the planning, operations and effective controls.*

*Records are maintained to show effective evidence of compliance.*

*The master copy (controlled copy) of the Standard Operating Procedures manual is kept by the Quality Manager and is available to all staff as required. Other copies may be produced by the author of the original in consultation with departments concerned and the Quality Manager.*

*Amendments to SOP’s must be authorised by the author of the original or their official designate. The Quality Manager must be advised of amendments in order that controlled copies can be updated.*

*Standards in use by the Organisation are the Organisation’s own standards and ISO 9001:2008.*

## 4.2.2. Quality Manual

The Organisation 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.
- b) The documented procedures established for the quality management system, or reference to them.
- c) A description of the interaction between the processes of the quality management system.

### 4.2.2

*This Quality Manual is the statement by the Organisation of its documented Quality System to conform to ISO 9001:2008.*

*Conformance with the requirements stated in this manual and in the Standard Operating Procedures is mandatory for everyone in the Organisation. Where improved methods and or procedures are identified, the documentation so affected will be officially and properly changed when agreement has been reached between all the functions concerned.*

*The Quality Manual is a controlled document, manuals are updated as required. It is the responsibility of the Quality Manager to ensure that a totally current manual is kept.*

*Reasons for, and details of changes are advised to keepers but the Quality Manager maintains the master record.*

*All sheets will carry issue status and amended sheets are signed by the author, Quality Manager, or designate.*

*No photocopies are allowed.*

### 4.2.3 Control of Documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be 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 determined by the organisation to be necessary for the planning and operation of the quality management system are identified and their distribution controlled.
- g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

### 4.2.3

*Documentation control is covered by documented procedures under the responsibility of the Quality Manager.*

## 4.2.4 Control of Records

Records to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. Records shall remain legible, readily identifiable and retrievable. The organisation shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

### 4.2.4

*Documented procedures exist to control the identification, storage, retrieval, protection and disposal of all records.*

*Records are maintained to give evidence that the Management System for the Organisation is operating correctly.*

*Management are responsible for ensuring that work has been carried out in line with procedures and that customer's requirements have been complied with.*

*All digital records are backed up.*

## **5 MANAGEMENT RESPONSIBILITY**

### **5.1 MANAGEMENT COMMITMENT**

Top Management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- a) Communicating to the Organisation the importance of meeting customer as well as statutory and regulatory requirements,
- b) Establishing the quality policy.
- c) Ensuring that quality objectives are established.
- d) Conducting management reviews.
- e) Ensuring the availability of resources.

### **5.1**

*Top Management direct the Organisation towards sustained customer satisfaction by satisfying its customers through products and services which comply with regulatory and legal requirements whilst recognising the needs of all interested parties.*

*The means of setting objectives, providing resources, directing, monitoring, and controlling the Organisation in a continuous improvement environment are described in this manual. The Organisation structure to discharge this is shown in the Organisation chart in this manual.*

### **5.2 CUSTOMER FOCUS**

Top Management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

### **5.2**

*Customer requirements are established through the enquiry and surveying process and communicated throughout the Organisation.*

## 5.3 QUALITY POLICY

Top Management shall ensure that the quality policy:

- a) Is appropriate to the purpose of the Organisation.
- b) Included 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 Organisation.
- e) Is reviewed for continuing suitability.

### 5.3

*The Quality Policy is communicated to all employees and is also displayed. It is reviewed periodically at Management Review Meetings.*

## 5.4 PLANNING

### 5.4.1 Quality Objectives

Top Management shall ensure that quality objectives, including those needed to meet requirements for products [see 7.1 (a)], are established at relevant functions and levels within the Organisation. The quality objectives shall be measurable and consistent with the quality policy.

#### 5.4.1

*These are part of the on going planning process being controlled by the Top Management and cascaded down throughout the Organisation. The quality objectives will be specific, measurable, achievable, realistic and time bound and consistent with the Quality Policy and are set at all levels and functions within the Organisation.*

## 5.4.2 Quality Management System Planning

Top Management shall ensure 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.
- b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

### 5.4.2

*The ongoing planning process accounts for the resources required to meet the objectives, plans any procedures required and identifies equipment, skills and training needed.*

*Appropriate measures, monitoring and records will apply and reviews of progress. Provisions for safety, potential liabilities, minimising risk to personnel, customers and the environment are made and reviewed at Management Review Meetings.*

## 5.5 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

### 5.5.1 Responsibility and Authority

Top Management shall ensure that responsibilities and authorities are defined and communicated within the Organisation.

#### 5.5.1

*The company shall ensure that all employees have a Job Description.*

*The overall Organisation Chart of the organisation is contained in this manual and updated as and when necessary.*

## 5.5.2 Management Representative

Top Management shall appoint a member of the organisation's management who, irrespective of other responsibilities, shall have 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.
- c) Ensuring the promotion of awareness of customer requirements throughout the Organisation.

NOTE: The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

## 5.5.2

*The Quality Manager is the quality management representative and is responsible for:*

1. *Preparation and maintenance of the Quality Manual.*
2. *Ensuring the quality system is implemented and maintained.*
3. *Reporting to management on the quality system and the need for improvement.*
4. *Maintaining awareness of customer needs.*

## 5.5.3 Internal Communication

Top Management shall ensure that appropriate communication processes are established within the Organisation and that communication takes place regarding the effectiveness of the quality management system.

## 5.5.3

*All information shall be transmitted to all relevant personnel through:*

- *Regular Meetings*
- *Email*
- *Notice Board*

## 5.6 MANAGEMENT REVIEW

### 5.6.1 General

Top Management shall review the Organisation's quality management system at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

### 5.6.1

*Documented Management Reviews of the system take place at defined intervals to ensure its continuing suitability and effectiveness.*

*A comprehensive preset agenda is followed and minutes taken.*

## 5.6.2 Review Inputs

The input to management review shall include 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.
- g) Recommendations for improvements.

### 5.6.2

*Reviews and audits are designed to ensure the Organisation's management system as described in this manual, in Standard Operating Procedures and various instructions remain effective, thus enabling the Organisation's objectives to be met.*

*Where major nonconformities are identified through critical examination of the reports, corrective measures are implemented.*

*A formal review of the Management System is undertaken, at defined intervals, by following a set agenda which considers the following areas:*

- *Audits*
- *Management objectives*
- *Cost of poor performance*
- *Supplier assessment*
- *Corrective and Preventive actions*
- *Commercial decision analysis*
- *Customer feedback and complaints*
- *Improvement recommendations*

### 5.6.3 Review Outputs

The output from the management review shall include 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.
- c) Resource needs.

### 5.6.3

*The results of the management review process are analysed to ensure a continual improvement to the system and products and services to customers.*

*In addition to the Management Reviews, Management also review of the objectives on an ongoing basis.*

## **6 RESOURCE MANAGEMENT**

### **6.1 PROVISION OF RESOURCES**

The Organisation shall determine and provide the resources needed:

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

#### **6.1**

*Appropriate resources (human, financial, equipment, information, infrastructure and environment) necessary for the implementation of policies and management systems to ensure the achievement of objectives are defined and reviewed at Management Review Meetings.*

*These resources are applied to managing the Organisation, processes and projects.*

*The aim is to enhance customer satisfaction by defining and meeting customer requirements.*

### **6.2 HUMAN RESOURCES**

#### **6.2.1 General**

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE: Conformity to product requirements may be affected directly or indirectly by personnel performing any task within the quality management system.

#### **6.2.1**

*The Management is responsible for guiding and advising the Organisation on human resource matters.*

*The selection and assignment of personnel to ensure applicable competence is on the basis of education, training, experience and personality.*

*There is effective designation and communication of responsibilities, authorities and functions to facilitate the efficient operation of the Organisation.*

## 6.2.2 Competence, Training and Awareness

The Organisation shall:

- a) Determine the necessary competence for personnel performing work affecting conformity to product requirements,
- b) Where applicable provide training or take other actions to achieve the necessary competence,
- c) Evaluate the effectiveness of the actions taken,
- d) Ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) Maintain appropriate records of education, training, skills and experience (see 4.2.4).

### 6.2.2

*The development of qualifications and competence is undertaken to meet the needs of the Organisation and its people.*

*Continual improvement is an Organisation strategy and awareness is promoted to ensure policies, objectives and motivation is enhanced and reflected in the products and services.*

*Training assessments are carried out on a regular basis and are recorded to ensure personnel are competent in the work that they do.*

*Training is done by internal and external courses, self learning packages and manuals.*

## 6.3 INFRASTRUCTURE

The Organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- a) Buildings, workspace and associated utilities.
- b) Process equipment ( both hardware and software).
- c) Supporting services (such as transport, communication or information systems).

### 6.3

*The infrastructure (plant, workspace, hardware, software, tools, standards, communication, transport and facilities) are determined by the requirement to deliver the Organisation's products and services.*

*The infrastructure requirements (function, performance, safety, security, availability, space, equipment and cost) are established, installed, maintained and reviewed.*

*Other issues are dealt with in the normal management authority chain appropriate to operating in a well established infrastructure.*

*Suitable maintenance programmes operate to ensure the infrastructure operates to requirements.*

## 6.4 WORK ENVIRONMENT

The Organisation shall determine and manage the work environment needed to achieve conformity to product requirements.

NOTE: The term “work environment” relates to conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather)

### 6.4

*Human and physical factors of the work environment needed to ensure Organisational results and conformity of product and service are recognised and implemented.*

*To assist motivation and satisfaction the following factors are considered:*

#### *HUMAN*

- *Understanding objectives and how they affect performance and quality*
- *Safety rules and procedures*
- *Continual improvement, greater involvement and realising potential*
- *Recognition and rewards for achievement and improvement*
- *Competence development*

#### *PHYSICAL*

- *Noise*
- *Heat*
- *Light*
- *Cleanliness*

## 7 PRODUCT REALISATION

### 7.1 PLANNING OF PRODUCT REALISATION

The Organisation shall plan and develop the processes needed for product realisation. Planning of product realisation shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realisation, the Organisation shall determine the following, as appropriate:

- a) Quality objectives and requirements for the product.
- b) The need to establish processes and documents to provide resources specific to the product.
- c) Required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance.
- d) Records needed to provide evidence that the realisation processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the Organisation's method of operations.

NOTE 1: A document specifying the processes of the quality management system (including the product realisation processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2: The Organisation may also apply the requirements given in 7.3 to the development of product realisation processes.

### 7.1

*Documented work instructions, where necessary, are available to personnel to whom they apply. All work is carried out in line with defined plans and/or procedures.*

*Equipment and materials used are assessed for suitability and compatibility with requirements.*

*Specifications are used to define acceptance criteria along with industry standards and legal requirements.*

## 7.2 CUSTOMER RELATED PROCESSES

### 7.2.1 Determination of Requirements Related to the Product

The Organisation shall determine:

- 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 applicable to the product.
- d) Any additional requirements considered necessary by the Organisation.

NOTE: Post delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

### 7.2.1

*Processes are established to identify customer requirements in terms of products/services, legal/regulatory obligations, commercial and matters of fitness for purpose, including any additional requirements decided by the Organisation.*

## 7.2.2 Review of Requirements Related to the Product

The Organisation shall review the requirements related to the product. This Review shall be conducted prior to the Organisation's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:

- a) Product requirements are defined.
- b) Contract or order requirements differing from those previously expressed are resolved.
- c) The Organisation has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the Organisation before acceptance.

Where product requirements are changed, the Organisation shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

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

### 7.2.2

*Contact is maintained with customers and users of the Organisation's products and services by relevant staff.*

*Orders are accepted into the Organisation only after a review has been made of the Organisation's ability to meet customer requirements.*

*Quotations are given by appropriate means and orders accepted against quotations or amended quotations.*

*Written quotations and orders are given a unique number.*

*Records are maintained of all orders and contracts.*

*Reference Flow Chart Process*

## 7.2.3 Customer Communication

The Organisation shall determine and implement effective arrangements for communicating with customers in relation to:

- a) Product information.
- b) Enquiries, contracts or order handling, including amendments.
- c) Customer feedback, including customer complaints.

### 7.2.3

*Effective Customer communication is achieved through:*

- *Trained personnel*
- *Website*
- *Brochure*
- *Complaints procedure*
- *Customer satisfaction survey*

## 7.3 DESIGN AND DEVELOPMENT

### 7.3.1 Design and Development Planning

The Organisation shall plan and control the design and development of product.

During the design and development planning, the Organisation shall determine:

- a) The design and development stages.
- b) The review, verification and validation that is appropriate to each design and development stage.
- c) The responsibilities and authorities for design and development.

The Organisation shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

NOTE: Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organisation.

### 7.3.1

*The design policy of the Organisation is to make use of proven design techniques, while taking every precaution to ensure that the product or service is fit for its use, and where applicable, satisfies legal/statutory and customers specified requirements.*

### 7.3.2 Design and Development Inputs

The inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include:

- a) Functional and performance requirements.
- b) Applicable statutory and regulatory requirements.
- c) Where applicable, information derived from previous similar designs.
- d) Other requirements essential for design and development.

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

### 7.3.2

*Where contracts require it, a quality plan will be prepared, reviewed and maintained. All requirements and other design inputs will be identified and recorded.*

### 7.3.3 Design and Development Outputs

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall:

- 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.
- d) Specify the characteristics of the product that are essential for its safe and proper use.

NOTE: Information for production and service provision can include details for the preservation of product.

### 7.3.3

*Designers must clearly state the outputs required and what the acceptance criteria are.*

*This information should be relayed to personnel in critical areas, in particular those affecting safety, performance, interchangeability and operability.*

### 7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development shall be 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,.
- b) To identify any problems and propose necessary actions.

Participants in such reviews shall 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 shall be maintained (see 4.2.4).

### 7.3.4

*Throughout the planning stages, points are defined during the design programme when a review should be undertaken where specific features of design are addressed.*

*This may be initiated by the Quality team, Management, Customer representative or associated personnel.*

### 7.3.5 Design and Development Verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4)

### 7.3.5

*The design team use various methods in order to determine that the product is fit for use, including prototype testing, dimensional analysis and Customer approval.*

*The design programme identifies whether the review is for stage verification or total design verification.*

### 7.3.6 Design and Development Validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

#### 7.3.6

*Design validation is achieved from the tests and from the continuing collection of data from users and field trials.*

### 7.3.7 Control of Design and Development Changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and products already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

#### 7.3.7

*A design change is treated exactly as the original design and must undergo the same approval.*

## 7.4 PURCHASING

### 7.4.1 Purchasing Process

The Organisation shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realisation of the final product.

The Organisation shall evaluate and select suppliers based on their ability to supply product in accordance with the Organisation's requirements. Criteria for selection, evaluation and re evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

#### 7.4.1

*A list of Approved Suppliers is in place following evaluation and selection and as a result of this all personnel within the organisation are aware of where to source approved goods and services to ensure conformity of product.*

*Suppliers are assessed on a regular basis at Management Review Meetings.*

### 7.4.2 Purchasing Information

Purchasing information shall describe the product to be purchased, including where appropriate:

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

The Organisation shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

#### 7.4.2

*Purchase orders clearly state the identification of the requirements, including approval requirements for product or qualification of personnel.*

### 7.4.3 Verification of Purchased Product

The Organisation shall establish and implement the inspection or other activities necessary for ensuring that purchased products meet specified purchase requirements.

Where the Organisation or its customer intends to perform verification at the supplier's premises, the Organisation shall state the intended verification arrangements and method of product release in the purchasing information.

### 7.4.3

*The Organisation shall ensure that all purchased products are verified or inspected to ensure specified requirements are met.*

*As and when verification can only take place at the suppliers premises arrangements shall be put in place to ensure product conformity.*

## 7.5 PRODUCTION AND SERVICE PROVISION

### 7.5.1 Control of Production and Service Provision

The Organisation shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:

- 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 equipment.
- e) The implementation of monitoring and measurement.
- f) The implementation of product, release, delivery and post-delivery activities.

### 7.5.1

*Operations and Services are controlled through:*

- *Availability of information regarding customer requirements and products*
- *Availability of departmental operating procedures*
- *The use and maintenance of suitable equipment*
- *Availability and maintenance of measuring and testing equipment*
- *Implementation of inspection activities*
- *Implementation of defined processes for release, delivery and repair/servicing of product*

## 7.5.2 Validation of Processes for Production and Service Provision

The Organisation shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and as a consequence deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The Organisation shall demonstrate the ability of these processes including, as applicable:

- 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).
- e) Re validation.

### 7.5.2

*Where product deficiency can only be determined after in use or service to minimise the incidence the following are undertaken:*

*The Organisation ensures that all relevant personnel are suitably qualified and the equipment used is "fit for purpose". Where appropriate an in-process inspection is carried out and results are maintained.*

### 7.5.3 Identification and Traceability

Where appropriate, the Organisation shall identify the product by suitable means throughout product realisation.

The Organisation shall identify the product status with respect to monitoring and measurement requirements throughout product realisation.

Where traceability is a requirement, the Organisation shall control the unique identification of the product and maintain records (see 4.2.4).

NOTE: In some industry sectors, configuration management is a means by which identification and traceability are maintained.

### 7.5.3

*All purchased products carry identification from the supplier and are accompanied by documentation regarding the source.*

*Products and services supplied by the Organisation are provided with unique numbers.*

## 7.5.4 Customer Property

The Organisation shall exercise care with customer property while it is under the Organisation's control or being used by the Organisation. The Organisation shall identify, verify, protect and safeguard 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, the organisation shall report this to the customer and maintain records (see 4.2.4).

NOTE: Customer property can include intellectual property and personal data.

### 7.5.4

*If and when a customer supplies product or service, it is treated as if it is purchased product or service and so is subject to the same checks and preservation on receipt as purchased product or service.*

*If at any time the product or service exhibits any sign of nonconformity, this will be reported to the customer.*

## 7.5.5 Preservation of Product

The Organisation shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

### 7.5.5

*Product is stored in accordance with recommended environmental storage conditions.*

*To facilitate traceability, each customer and contract has unique identification, which is recorded.*

## 7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

The Organisation shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The Organisation shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measuring requirements.

Where necessary to ensure valid results, measuring equipment shall:

- a) Be calibrated or verified or both 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 ( see 4.2.4);
- b) Be adjusted or re-adjusted as necessary.
- c) Have identification in order to determine its calibration status.
- d) Be safeguarded from adjustments that would invalidate the measurement result.
- e) Be protected from damage and deterioration during handling, maintenance and storage.

In addition, the Organisation shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The Organisation shall take appropriate action on the equipment and any product affected.

Records of the results of calibration and verification shall be maintained (see 4.2.4)

NOTE: Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

### 7.6

*The Organisation undertakes calibration of equipment using a qualified subcontractor, all records are duly kept and readily available for inspection.*

## **8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT**

### **8.1 GENERAL**

The Organisation shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

- a) To demonstrate conformity to product requirements.
- b) To ensure conformity of the quality management system.
- c) To continually improve the effectiveness of the quality management system.

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

### **8.1**

*Measurement analysis and improvement processes are implemented as a means of demonstrating that products/services conform to requirements.*

*Each area of management responsibility defines and records measures according to their importance and the results of data analysis, together with improvements are used as inputs to the management review process.*

## **8.2 MONITORING AND MEASUREMENT**

### **8.2.1 Customer Satisfaction**

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

NOTE: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims, dealer reports.

### **8.2.1**

*Actions shall be taken to determine the level of customer satisfaction and ascertain quality of product/service*

*Results are analysed at Management Review Meetings and actions taken where necessary to effect continual improvement.*

## 8.2.2 Internal Audits

The Organisation shall conduct 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 this International Standard and to the quality management system requirements established by the Organisation.
- b) Is effectively implemented and maintained.

An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained (4.2.4).

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

## 8.2.2

*Internal Audits are pre-planned on a rolling plan basis to take account of other audits.*

*It is Organisation policy that the auditor is independent of the area being audited, but that the auditor may be accompanied by a representative of the area.*

*Any non conformity found during internal audits will be reported to the manager of the area concerned.*

*All non conformities will be reported to the Quality Manager and corrective action taken without undue delay. All corrective actions shall be followed up to ensure any changes implemented are being observed*

*A Standard Operating Procedure is in place to cover the operation of internal audits.*

### 8.2.3 Monitoring and Measurement of Processes

The Organisation shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE: When determining suitable methods, it is advisable that the organisation consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

#### 8.2.3

*The resulting outputs of all processes are verified by inspection, testing and monitoring by the Management.*

*Data is collected from internal audits which is analysed and corrective action taken when needed.*

*All data collated is analysed and reviewed at Management Review Meetings.*

### 8.2.4 Monitoring and Measurement of Product

The Organisation shall monitor and measure the characteristics of the product requirements and ensure that they have been met. This shall be carried out at appropriate stages of the product realisation process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorising release of product for delivery to customer (see 4.2.4).

The release of product and delivery of service shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

#### 8.2.4

*Product is monitored and measured to ensure it meets with customer requirements with records maintained.*

*Customer acceptance criteria are recorded and records show the authority responsible for the release of product.*

## 8.3 CONTROL OF NONCONFORMING PRODUCT

The Organisation shall ensure that any product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable the Organisation shall deal with nonconforming product by one or more of the following ways:

- a) By taking action to eliminate the detected nonconformity.
- b) By authorising its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer.
- c) By taking action to preclude its original intended use or application.
- d) By taking action appropriate to the effects, or potential effects of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the Organisation shall take action appropriate to the effects, or potential effects, of the nonconformity.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

### 8.3

*To prevent non-conformance in-process inspection takes place at regular intervals and any nonconformities rectified prior to entering the delivery chain Product is again inspected before release.*

*All non conformities are reported to the Quality Manager in order that trends can be noticed and corrective action taken.*

*Disposition can only be decided by the author of the specification and any concession must be advised to the Quality Manager together with the reason.*

*Goods received from suppliers and found to be nonconforming are quarantined and only taken out of quarantine when deemed to be fit for purpose.*

## 8.4 ANALYSIS OF DATA

The Organisation shall determine, collect and analyse 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 shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to:

- a) Customer satisfaction (see 8.2.1).
- b) Conformity to product requirements (see 8.2.4).
- c) Characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4).
- d) Suppliers (see 7.4).
- e) Please refer to the Continual Improvement Model located on page 52 of this Quality Manual

## 8.4

*The Organisation analyse data in order to identify areas for improvement.*

*Data is collected from management information, audits, corrective and preventive actions, nonconforming product/service, customer satisfaction reports and supplier assessment*

*Analysis of the data provides information on:*

- *Effectiveness of the quality management system*
- *Process operation trends*
- *Customer satisfaction*
- *Conformance to customer requirement*
- *Suppliers*

## 8.5 IMPROVEMENT

### 8.5.1 Continual Improvement

The Organisation shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

#### 8.5.1

*Data relating to the quality management system shall be collated and analysed both on an ongoing basis and at management review.*

*From this data analysis key performance indicators shall be set and this will measure the effectiveness of the quality management system and determine the level of continuous improvement.*

### 8.5.2 Corrective Action

The Organisation shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be 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).
- f) Reviewing the effectiveness of the corrective action taken.

#### 8.5.2

*Corrective actions can arise from any situation found to conflict with quality.*

*The quality team will address all quality related problems and ensure prompt, effective and durable corrective action is taken where necessary.*

*A documented procedure has been established for the control of corrective action.*

### 8.5.3 Preventive Action

The Organisation shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be 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).
- e) Reviewing the effectiveness of the preventive action taken.

### 8.5.3

*Data relating to process problems, audit results, customer complaints, etc. is collected and analysed and possible trends recognised.*

*The Quality Manager will nominate suitable persons to deal with any problems requiring preventive action.*

*A documented procedure has been established for the control of preventive action.*

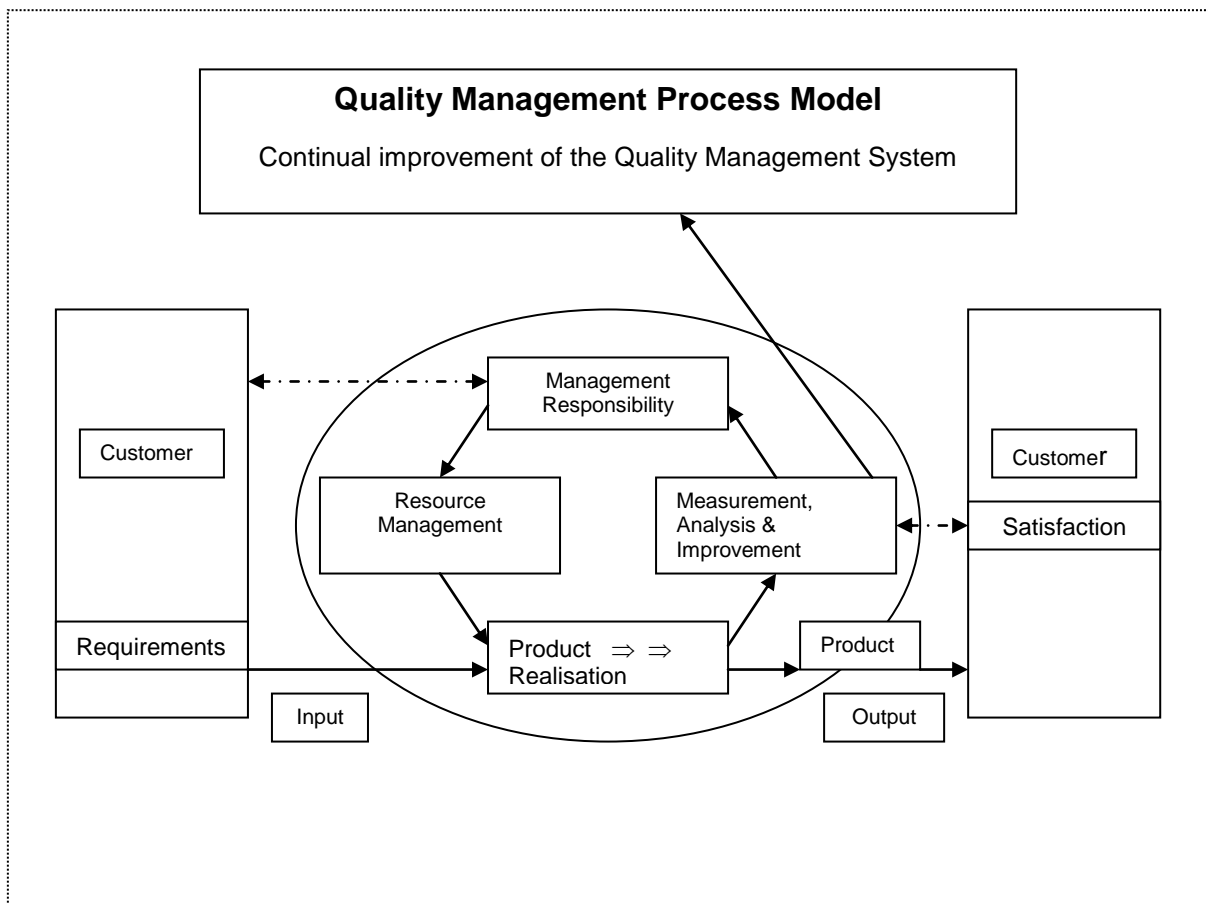
## ISO 9001 : 2008 STRUCTURE

| <b>Terms &amp; Definitions</b> |  |
|--------------------------------|--|
| Audit                          | Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which agreed criteria are fulfilled |
| Auditor                        | One or more auditors conducting an audit   |
| Audit Criteria                 | Set of policies, procedures or requirements used as a reference  |
| Audit evidence                 | Records, statements of fact or other information which are relevant to the audit criteria and verifiable   |
| Audit Team                     | Persons or groups of persons conducting an audit   |
| Conformity                     | Fulfilment of a requirement  |
| Corrective Action              | Action taken to eliminate the cause of a detected nonconformity or other undesirable situation   |
| Customer                       | Organisation or person that receives a product   |
| Design and Development         | Set of processes that transforms requirements into specified characteristics or into the specification of a product or process   |
| Objective Evidence             | Data supporting the existence or verity of something   |
| Organisation                   | Group of people and facilities with an arrangement or responsibilities, authorities and relationships  |
| Process                        | Set of interrelated or interacting activities which transforms inputs into outputs   |
| Product                        | Output of an Organisation which can also be a service  |
| Quality                        | Degree to which a set of inherent characteristics fulfils requirements   |
| Quality Assurance              | Part of quality management, focused on providing confidence that quality requirements will be fulfilled  |

## ISO 9001 : 2008 STRUCTURE - Continued

| <b>Terms &amp; Definitions</b> |  |
|--------------------------------|--|
| Quality Control                | Part of quality management focused on fulfilling quality requirements  |
| Quality Management             | Coordinated activities to direct and control an Organisation with regard to quality  |
| Quality Manual                 | Document specifying the quality management system of an Organisation   |
| Quality Plan                   | Document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract                    |
| Quality Planning               | Part of quality management focused on setting quality objectives and specifying necessary operational processes and related resources to fulfil the quality objectives |
| Quality Policy                 | Overall intentions and direction of an Organisation related to quality as formally expressed by top management   |
| Specification                  | Document stating requirements  |
| Supplier                       | Organisation or person that provides a product   |
| Validation                     | Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled                        |
| Verification                   | Confirmation through the provision of objective evidence that specified requirements have been fulfilled   |

## The Quality Management Process



## Continual Improvement

