

# 1 INTRODUCTION TO QUALITY MANAGEMENT

This section will introduce you to the basic concepts and definitions in Quality Management. The scope and contents of the Standards from the ISO 9000 series are summarized.

We encourage you to read carefully all the concepts and definitions. Try to identify how these concepts or actions apply to the specifics of your work. Some examples are given for illustration.

What is relevant at this stage is to provide you with a general picture about Quality Management, and to make you realize what you are still missing in your practice. The following section will guide you to identify simple actions aimed to ensure the quality of your work, whilst Section 3 will provide guidance to implement a system fitting to the purposes of Electronics practice.

## 1.1 THE GOAL OF QUALITY MANAGEMENT

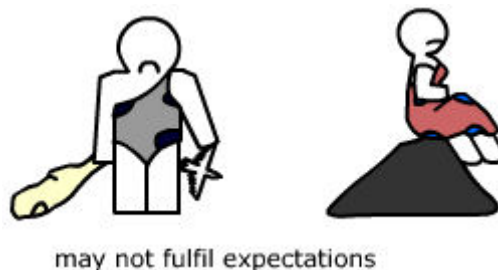
To lead and operate an **organization** successfully, it is necessary to direct and control it in a systematic and transparent manner.

Success can result from implementing and maintaining a **management system** that is designed to continually improve performance while addressing the needs of all interested parties (**customer** and **supplier**).

*MANAGING AN ORGANIZATION ENCOMPASSES QUALITY MANAGEMENT (QM) AMONGST OTHER MANAGEMENT DISCIPLINES.*

## 1.2 THE EARLIEST DEFINITION OF QUALITY

"How GOOD it is..." (Stone Age man,  $\geq 10\ 500$  years BP)



Since then, and despite the evolution of the language, there were always misunderstandings and conflicts of interests. The need for an agreement in the definition of quality grew and grew...

### 1.3 THE DEFINITION OF QUALITY AS CONSENSUALLY AGREED BY 2005 (ISO 9000)

"The degree to which a set of *inherent* characteristics fulfils *requirements*"

- Quality can be used with adjectives such as poor, good, excellent...
- '**Inherent**', as opposed to '**assigned**', means existing in something, especially as a permanent characteristic...
- '**Requirement**': A need or expectation that is **stated, generally implied** or obligatory
- **Stated** means usually explicitly in a document.
- **Generally implied** means that it is custom or common practice for the organization, its customers and other interested parties.
- **Requirement** is the expression in the content of a document conveying criteria to be fulfilled if compliance with the document is to be claimed and from which no deviation is permitted.

### 1.4 ISO 9000:2005. LOOKING FOR A CONSENSUS

ISO 9000 standard series was developed to assist organizations, of all types and sizes, to implement and operate effective quality management systems.

*ISO 9000:2005 DEFINES GENERAL, FUNDAMENTAL ISSUES.*

### 1.5 ISO 9000:2005 CONTENTS

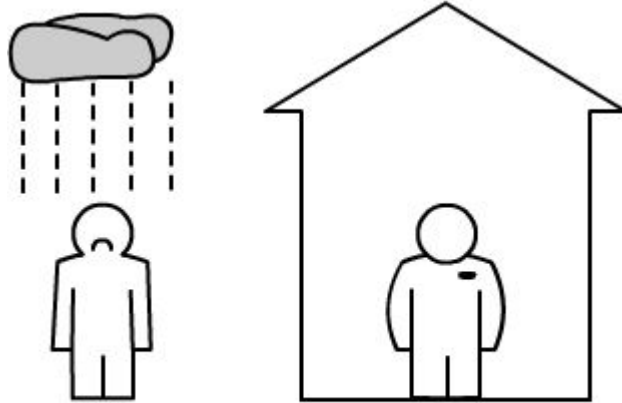
- **Fundamentals:**
  - Rationale
  - Requirements for QMS
  - Requirements for products
  - QMS approach
  - Process approach
  - Quality policy and quality objectives
  - Role of top management
  - Documentation
  - Evaluation of QMS
  - Continual improvement
  - Role of statistical techniques
- **Terms and definitions**

### 1.6 THE EIGHT QM KEY PRINCIPLES

- Customer focus
- Leadership
- People involvement
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationships

### 1.6.1 QM KEY PRINCIPLES: CUSTOMER FOCUS

Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.



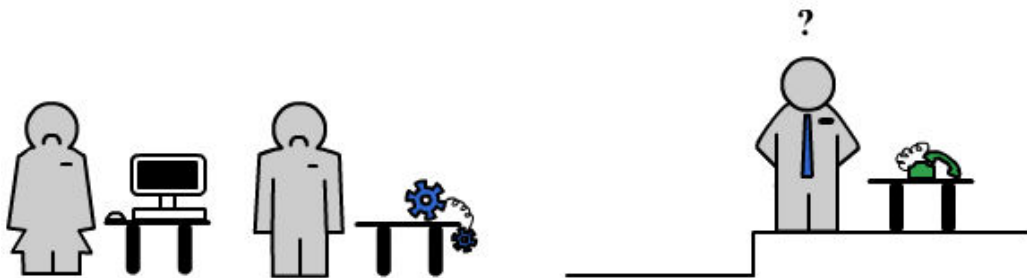
The management shall identify the customer needs...

*THE CUSTOMER IS ALWAYS RIGHT!*

### 1.6.2 QM KEY PRINCIPLES: LEADERSHIP

Leaders establish unity of purpose and direction of the organization.

- Leaders should create and maintain the internal environment in such a way that people can become fully involved and committed in achieving the organization's objectives.

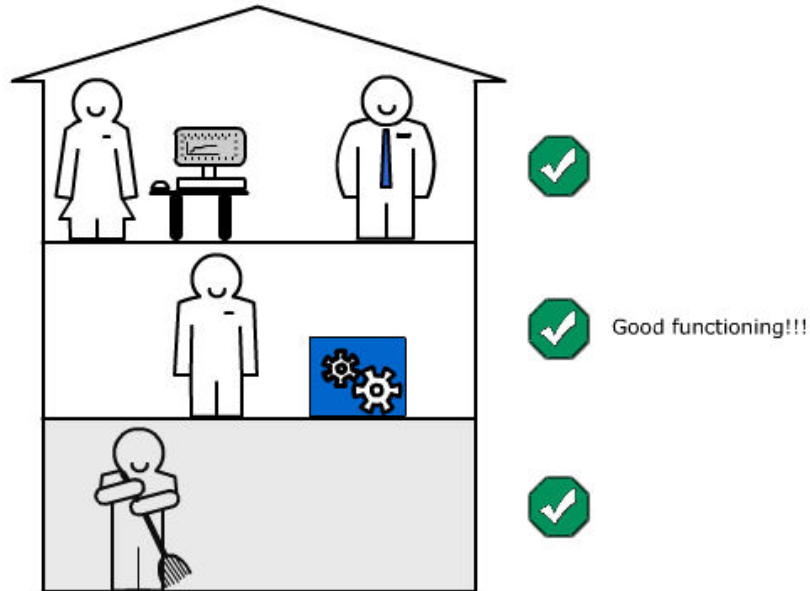


Concerning about the organization needs...

*TO BECOME A REAL LEADER, NOT JUST THE BOSS!*

### 1.6.3 QM KEY PRINCIPLES: PEOPLE INVOLVEMENT

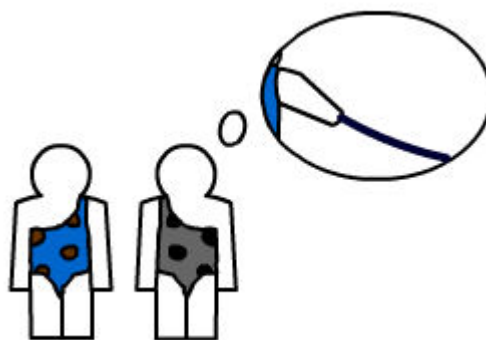
People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.



*IT'S EVERYBODY'S BUSINESS. UNITY MAKES STRENGTH.*

### 1.6.4 QM KEY PRINCIPLES: PROCESS APPROACH

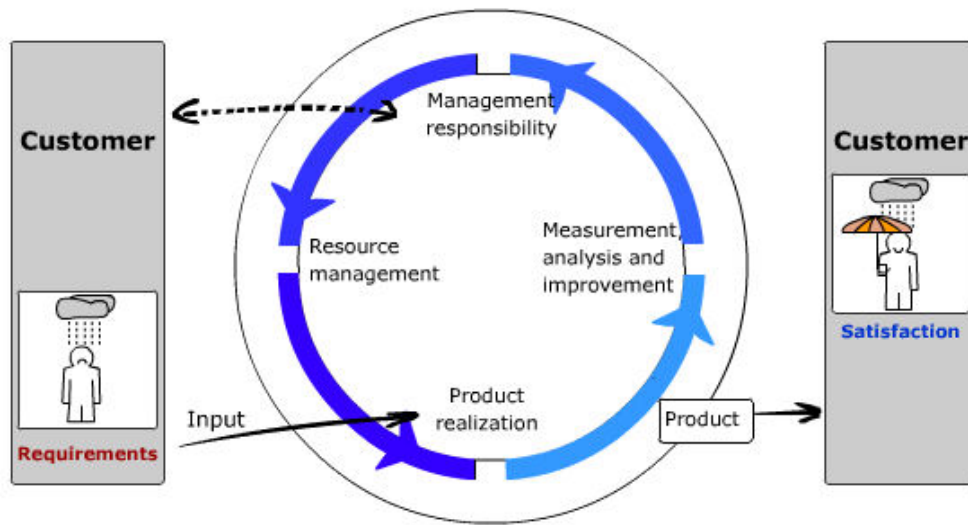
A desired result is achieved more efficiently when activities and related resources are managed as a **process**.



*PROCESS APPROACH IS BASED IN THE PDCA PRINCIPLE: PLAN ► DO ► CHECK ► ACT*

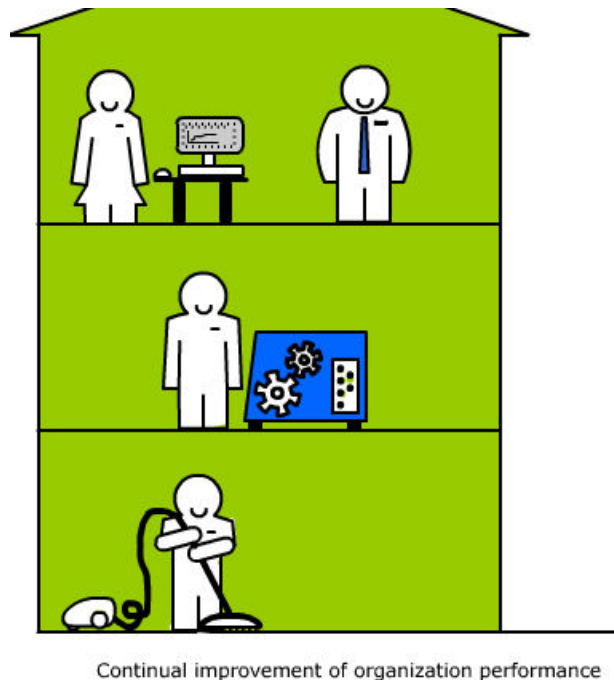
1.6.5 QM KEY PRINCIPLES: SYSTEM APPROACH TO MANAGEMENT

Identifying, understanding and managing interrelated processes as a **system** contributes to the organization's **effectiveness** and **efficiency** in achieving its objectives.



1.6.6 QM KEY PRINCIPLES: CONTINUAL IMPROVEMENT

Continual improvement of the organization's overall performance should be a permanent objective.



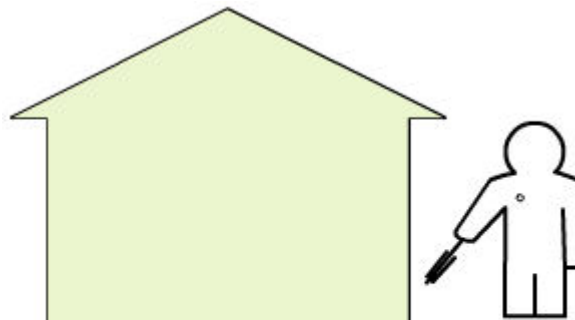
*WE ARE GOOD... BUT WE CAN BE EVEN BETTER!*

1.6.7 QM KEY PRINCIPLES: FACTUAL APPROACH TO DECISION MAKING  
Effective decisions are based on the analysis of data and **information**.



*WE BELIEVE IN PEOPLE... BUT MUCH MORE IN THE FACTS.*

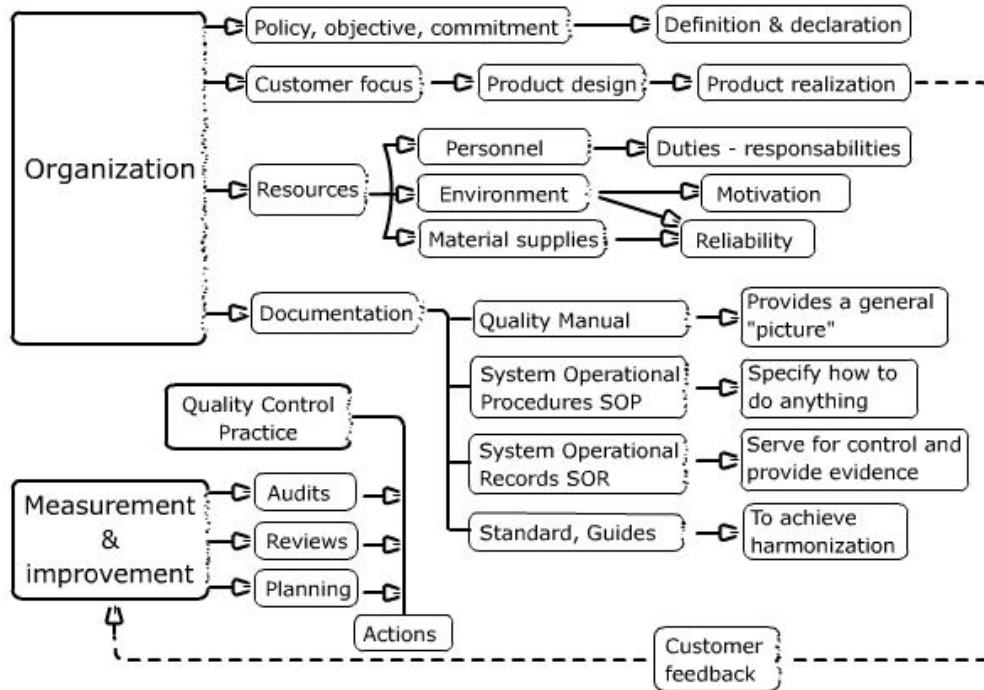
1.6.8 QM KEY PRINCIPLES: MUTUALLY BENEFICIAL SUPPLIER RELATIONSHIPS  
An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.



all the suppliers must be 'motivated'

*ONE HAND WASHES THE OTHER... AND BOTH WASH THE BODY!*

### 1.7 KEY ELEMENTS IN QUALITY MANAGEMENT



### 1.8 QUALITY MANAGEMENT CONNOTATIONS

- Ethic value (performing at own best effort!).
- Documented **procedures** and **records** help to ensure traceability and dependability.
- Mutually beneficial outcome for supplier and customers.
- **Customer satisfaction** increases.
- Supplier organization efficiency, competence and **capabilities** enhance continuously.

### 1.9 OTHER RELEVANT QUALITY STANDARDS FROM THE ISO 9000 SERIES:

**ISO 9001:2000.** Quality Management Systems – Requirements.

**ISO/IEC 17025:2005.** General requirements for the competence of testing & calibration laboratories.

#### 1.9.1 INTRODUCTION TO THE ISO 9001:2000

#### **ISO 9001:2000 Quality Management Systems – Requirements**

This Standard specifies the requirements for a QMS where an organization needs to demonstrate its ability to consistently provide product that meets customer and regulatory requirements, and aims to enhance customer satisfaction through the effective application of the QMS, including processes for continual improvement and the assurance of conformity to customer and applicable regulatory requirements.

*CONFORMITY TO THIS STANDARD DOES NOT ITSELF DEMONSTRATE THE COMPETENCE OF THE LABORATORY TO PRODUCE TECHNICALLY VALID DATA AND RESULTS IN TESTS OR CALIBRATIONS.*

## 1.9.1.1 CONTENTS OF ISO 9001:2000

**QMS:**

- General requirements
- Requirements for documentation

**Management:**

- Management commitment
- Customer focus
- Quality policy
- Planning
- Responsibility, authority and communication
- Review

**Resources:**

- Provision
- Human resources
- Infrastructure
- Work environment

**Product realization:**

- Planning
- Customer-related processes
- Design and development
- Purchasing
- Production and service provision
- Control of monitoring and measuring devices

**Measurement, analysis and improvement:**

- Monitoring and measurement
- Control of nonconformities
- Analysis of data
- Improvement

*PROCESS APPROACH: PLAN ► DO ► CHECK ► ACT*

## 1.9.1.2 GENERAL REQUIREMENTS

The organization shall:

- identify the processes needed for the QMS and their application, throughout the organization.

**examples of processes are:**

- personnel
- spare parts and components
- instruments for calibration, measurement of electrical magnitudes
- tools
- locals and installations

- determine the sequence and interaction of these processes.
- determine the criteria and methods needed to ensure that both the operation and control of these processes are effective.



- ensure the availability of the resources and **information** necessary to support the operation and monitoring of such processes.

**resources are:**

- operational procedures and working instructions
- service manuals
- catalogues of spare parts
- inventory and other type of records

- monitor, measure and analysis these processes, and
- implement actions aimed to achieve planned results and **continual improvement** of these processes.

**actions may be:**

- audits
- management reviews
- technical meetings and discussions
- corrective actions.

### 1.9.1.3 DOCUMENTATION REQUIREMENTS

The QMS documentation shall include:

- documented statements of the quality policy and quality objectives, which can be included in:
- a Quality Manual.
- documented procedures describing the QMS processes and technical procedures.
- documentation needed to ensure the effective planning, operation and control of these processes, and
- records to provide evidence of the carried out processes. The extent of the QMS documentation depends on the size of the organization, the type of its activities, the complexity of the processes and their interactions.

*THE EXTENT OF THE QMS DOCUMENTATION DEPENDS ON THE SIZE OF THE ORGANIZATION, THE TYPE OF ITS ACTIVITIES, THE COMPLEXITY OF THE PROCESSES AND THEIR INTERACTIONS.*

#### 1.9.1.3.1 THE QUALITY MANUAL

The Quality Manual shall include:

- the scope of the QMS, including details and justifications for any exclusions.
- the documented procedures established for the QMS or references to them.
- a description of the interactions between the processes of the QMS.

#### 1.9.1.3.2 CONTROL OF DOCUMENTS

A documented procedure shall be established to define the controls needed:

- to approve any documents for adequacy prior to use.
- to review, update and re-approve the documents whenever necessary.
- to ensure that changes and current version status are identified.
- to ensure that relevant versions of the documents are available (documentation history).
- to ensure that documents remain legible and readily identifiable.

- to ensure that documents of external origin are identified and their distribution controlled.
- to prevent the unintended use of obsolete documents.

#### 1.9.1.3.3 CONTROL OF RECORDS

Records must be established and maintained to provide evidence of conformity to requirements and of effective operation of the QMS.

**examples of records:**

- inventory of parts and components
- inventory of instrumentation, its calibration (verification) and maintenance
- results of calibration works
- results of carried out services

A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of the records.

#### 1.9.1.4 MANAGEMENT COMMITMENT

**Top management** shall provide evidence of its commitment to the development and implementation of the QMS and continually improve its effectiveness by:

- communicating to the organization the importance of meeting customer requirements.
- ensuring that quality policy and quality objectives are established.
- ensuring the availability of resources.
- conducting management **reviews**.

#### 1.9.1.5 QUALITY POLICY

Top management shall ensure that quality policy:

- is appropriate for the purpose of the organization.
- includes a commitment to comply and continually improve the QMS effectiveness.
- provides a framework for establishing and reviewing quality objectives.
- is communicated and understood within the organization.
- is reviewed for continuing sustainability.

**The quality policy of an electronic laboratory could be defined as:** It is the policy of the Electronics Laboratory that its service support achieves a level of quality in execution and delivery of results that is commensurate with the requirements of its quality system. The Electronics Laboratory will endeavour to carry out electrical calibration of testing equipment and nuclear instruments and provide results that are at a quality level consistent with the international requirements. To achieve this, the top management will establish a Quality System in compliance with the ISO/IEC 17025:2005 and the ISO 9001 standards, and will ensure that all the members of the staff will be acquainted with the Quality System and the implemented procedures. The members of the laboratory will perform their work as to fulfil the requirements of the Quality Policy.

1.9.1.6 QUALITY PLANNING

Top management shall ensure that:

- quality objectives are established at relevant functions and levels within the organization
- quality objectives are measurable and consistent with the quality policy
- QMS planning is carried out to meet the general requirements and the quality objectives
- the integrity of the QMS is maintained when changes are planned and implemented

A Quality Management planning checklist for Electronics laboratory could include...

Do we have/ Do we do	Yes/No	QM Actions
A clear view of what our business is?	Y	None
A clear view of what our customer needs?	N	<ul style="list-style-type: none"> <li>• To contact customers (directly or via questionnaires)</li> <li>• To include in service requests template a request for requirements statement by the customer</li> </ul>
Good internal communication?	N	<ul style="list-style-type: none"> <li>• Install intercom/phone devices</li> <li>• To encourage direct communication among employees</li> </ul>
A clear organization structure?	Y	None
Is the work to be done met by individual competences?	N	<ul style="list-style-type: none"> <li>• To review staff CV</li> </ul>
A job description for each person?	Y	None
Plan for the training and development of each person?	N	<ul style="list-style-type: none"> <li>• To prepare individual plans of training activities</li> </ul>

1.9.1.7 RESPONSIBILITY, AUTHORITY AND COMMUNICATION

Top management shall ensure that:

- responsibilities and authorities are defined and communicated within the organization.
- a representative is appointed to have responsibility and authority for QMS issues (usually a quality management manager).
- appropriate communication processes are established within the organization and that communication takes place regardless the effectiveness of the QMS.

1.9.1.8 MANAGEMENT REVIEW

Top management shall review the QMS at planned intervals, to ensure its sustainability, adequacy and effectiveness. The reviews shall include assessing opportunities for improvement and the need for changes in the QMS.

Inputs	Outputs
-Results of <b>audits</b> -Customer feedback	Improvement of the effectiveness of the QMS and its processes
Process performance and product <b>conformity</b>	Improvement of the product regarding to customer requirements
Status of <b>preventive</b> and <b>corrective actions</b>	Resource needs
-Follow-up actions from previous reviews -Changes and recommendations for improvement	Approving changes and corrections

1.9.1.9 RESOURCE MANAGEMENT

The organization shall determine the resources needed for the realization of the product and for implementing and maintaining of the QMS. Resources include:

Type	Requirements
Human resources	Competence, awareness, training and involvement
Infrastructure (building, workspace, equipment, supporting services)	Quality ensuring to achieve conformity in product realization
Materials	

1.9.1.10 PLANNING PRODUCT REALIZATION

The organization shall plan and develop the processes required for product realization. Such planning must be consistent with both customer requirements and QMS requirements, thus including:

- **quality objectives** and **requirements** for the product.

**in the case of repair of instrumentation the service request shall include information on technical requirements, such as:**

- expected performance of the instrument after repair.
- description of instrument operation/actuators.
- special requirements for operation (if any).
- results expected for which date.

- the need to establish processes, documents and resource provision.

**you may take into account the following issues:**

- is there previous experience on similar task?
- plan of actions to perform the repair.
- search/procurement of technical documentation.
- availability of spare parts/alternative replacements.
- instrumentation for performance evaluation available?

- required **verification, validation**, monitoring, inspection and **test** activities specific to the product and the criteria for product acceptance.
- **records** needed to provide evidences that processes and the resulting product meet the requirements.

**examples of records:**

- service request.
- modifications to original request/plan of actions.
- results of internal quality control check.
- copy of delivered report of results/ customer acceptance.

1.9.1.11 CUSTOMER RELATED PROCESSES

In order to achieve customer satisfaction, the organization shall review the requirements related to the product prior to organization’s commitment to supply it to the customer and shall ensure that:

- product requirements are defined.
- contract or order requirements differing from those previously agreed are resolved.
- the organization has the ability to meet the agreed requirements.

*PRODUCT REQUIREMENTS SHALL COMPRISE THOSE SPECIFIED BY THE CUSTOMER (INCLUDING DELIVERY AND POST-DELIVERY ACTIVITIES), THOSE NOT SPECIFIED BY THE CUSTOMER BUT NECESSARY FOR THE INTENDED USE, STATUTORY OR REGULATORY REQUIREMENTS AND ANY ADDITIONAL REQUIREMENTS ESTABLISHED BY THE ORGANIZATION.*

1.9.1.12 COMMUNICATION WITH THE CUSTOMER

Effective arrangements shall be determined and implemented for communicating with the customer in regard to:

- product information.
- enquiries, contracts or other handling, including amendments to original order requirements.
- customer feedback, including complaints.



**a service request for repair of instrumentation can vary during the service completion.**

New failures can be found during troubleshooting, instrument aging can limit achieving the expected original performance of the instrument, spare parts might be not available, among other departures. Communication with the customer is therefore, a needed mean to agree modifications to the original requirements.

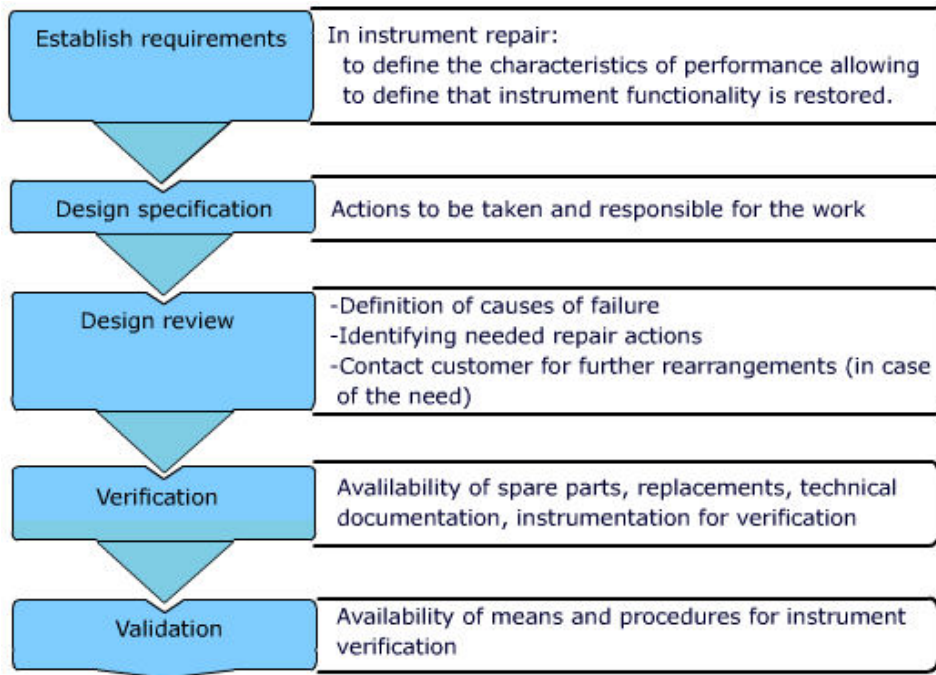
1.9.1.13 DESIGN AND DEVELOPMENT PLANNING

The organization shall plan and control the design and development of a product. The planning must establish:

- the design and development stages.
- the review, verification and validation to each design and development stage.
- the responsibilities and authorities for design and development.

PLANNING OUTPUT SHALL BE UPDATED AS THE DESIGN AND DEVELOPMENT PROGRESSES.

1.9.1.14 DESIGN AND DEVELOPMENT PLANNING STAGES



1.9.1.15 DESIGN AND DEVELOPMENT INPUTS/OUTPUTS

Inputs relating product requirements shall be determined and records maintained. Inputs shall be reviewed for adequacy and must be unambiguous and not in conflict with each other.

- inputs include:**
- functional and performance requirements
  - statutory and regulatory requirements, if applicable
  - information derived from similar designs.

The outputs of design and development shall be provided in a form allowing verification against inputs, and shall be approved prior to product release.

- outputs shall:**
- meet the input requirements.
  - provide information for purchasing, production and service provision.
  - contain or reference criteria for product acceptance.

**1.9.1.16 DESIGN AND DEVELOPMENT REVIEW, VERIFICATION AND VALIDATION**

At suitable stages, systematic reviews of design and development shall be performed, in order to evaluate if the results meet requirements and to identify any problems and to propose necessary actions.

Verification shall be performed to ensure that the design and development outputs have met the input requirements.

Validation shall be performed to ensure that the resulting product is capable of meeting the requirements for the specified operation or intended use.

*RECORDS OF REVIEW, VERIFICATION AND VALIDATION SHALL BE MAINTAINED.*

**1.9.1.17 PURCHASING PROCESS (OUTSOURCING)**

The organization shall ensure that any purchased product conforms to specified purchase requirements. The type and extent of the control applied to the supplier and purchased product depends on the effect that the purchased product may have in subsequent product realization.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements.

**for the repair of most of the nuclear instrumentation:**

The spare parts shall be supplied from the original manufacturer. However, replacements can be made for the case of failure of simple electronic components. Such components must have not only technical characteristics compatible with the original parts, but also have a quality not worst than the ones used in the original design, that means:

- fitness to customer technical specifications and quality requirements
- provide quality guarantee sufficient for the intended purpose
- acceptable cost/benefit ratio
- sustainability for long period of time.

*RECORDS ON THE EVALUATION OF THE PURCHASED PRODUCTS SHALL BE MAINTAINED.*

**1.9.1.18 PRODUCTION AND SERVICE PROVISION**

The organization shall plan and carry out production and service provision under controlled conditions, which shall include:

- the availability of information describing the characteristics of the product.
- the availability of work instructions (procedures).
- the use of suitable equipment.
- the availability and use of monitoring and measuring devices.
- the implementation of monitoring and measurement (quality control practice).
- the implementation of release, delivery and post-delivery activities.

*THE ORGANIZATION SHALL IDENTIFY THE PRODUCT THROUGHOUT ANY STAGE OF PRODUCT REALIZATION. FOR TRACEABILITY PURPOSES THE PRODUCT IDENTIFICATION SHALL BE UNIQUE AND KEPT IN RECORDS.*

1.9.1.19 CONTROL OF MONITORING AND MEASURING DEVICES

The organization shall determine the monitoring and measurements to be undertaken to provide evidence on the conformity of product to determined requirements. Where necessary to ensure valid results, measuring equipment shall:

- be calibrated or verified at specified intervals against measurement standards traceable to international or national standards.
- be adjusted or re-adjusted when necessary.
- be identified to enable the monitoring of the calibration status.
- be safeguarded to avoid adjustments that could breach the calibration status.
- be maintained under conditions preventing damage or deterioration.

**under such control must be:**

- oscilloscopes, multi-meters, counters, and other measuring instrument used for maintenance/repair works, and
- generators of signals used for calibrations.

1.9.1.20 MEASUREMENT, ANALYSIS AND IMPROVEMENT

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed.

**why?**

- to demonstrate conformity of the product
- to ensure conformity of the QMS, and
- to continually improve the effectiveness of the QMS

**some means that can be used for monitoring/measurement purposes are:**

- customer satisfaction, via customer feedback information (questionnaires)
- internal and external audits
- monitoring and measurement of the product.

1.9.1.21 CONTROL OF NONCONFORMITIES

The organization shall ensure that product that does not conform to requirements is identified and controlled to prevent its unintended use or delivery. The controls, related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

**Nonconformities** can be dealt in more than one way:

- by taking action to eliminate the detected nonconformity.
- by authorizing its use, release or acceptance under **concession** by a relevant authority or the customer.
- by taking action to preclude its original intended use or application.

*RECORDS OF THE NATURE OF NONCONFORMITIES AND ANY SUBSEQUENT ACTION TAKEN, INCLUDING CONCESSIONS OBTAINED, SHALL BE MAINTAINED.*

1.9.1.22 ANALYSIS OF DATA

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made.



The analysis of data generated as a result of monitoring and measurement shall provide information relating to:

- **Customer satisfaction.** Can be assessed by delivering questionnaires inquiring about customer’s opinions and suggestions.
- **Conformity to product requirements.** The repaired instrumentation must be always verified before been returned to the customer (internal quality control).
- **Characteristics and trends of processes and products including opportunities for preventive actions,** such as: modifications in basic circuits, improvements in electronic circuit design, or in components.
- Suppliers.

1.9.1.23 IMPROVEMENT

The organization shall continually improve the effectiveness of the QMS through the use of the quality police, quality objectives, audit results, analysis of data, corrective and preventive actions and management reviews.

	Corrective action	Preventive action
Cause	encountered nonconformity	foreseeing potential problems
Requirements to the associated documented procedure	reviewing nonconformities and causes actions needed (including those to prevent recurrence) records of actions taken review of the taken action	determining potential nonconformities & causes

1.9.1.24 SUMMARY ON ISO 9001

You must have learned that ISO 9001 provides instructions and recommendations aimed to implement a Quality Management System ensuring that:

- the realization of a product is accomplished in a way that such product complies with customer and/or regulatory requirements, and
- the system includes processes for continual improvement.

1.9.2 INTRODUCTION TO THE ISO/IEC 17025:2005

**ISO/IEC 17025:2005 General requirements for the competence of testing & calibration laboratories**

This Standard specifies the requirements for the competence to carry out tests and calibrations (including sampling). It covers the use of standard, non-standard and laboratory developed methods. The standard is meant to be used in developing the laboratory QMS, the administrative and technical operations.

*COMPLIANCE TO THIS STANDARD IMPLIES OPERATION IN ACCORDANCE WITH ISO 9001.*

*CONFORMITY TO THIS STANDARD DOES NOT IMPLY CONFORMITY OF THE LABORATORY QMS TO ALL THE REQUIREMENTS OF ISO 9001.*

### 1.9.2.1 CONTENTS OF ISO/IEC 17025:2005

#### Management requirements:

- Organization
- Management system
- Document control
- Review of request, **contracts** and tenders
- Subcontracting **tests**/calibrations
- Purchasing services/supplies
- Services to the customer
- Complaints
- Control of nonconformities
- Improvement
- **Corrective actions**
- **Preventive actions**
- Control of **records**
- **Internal audits**
- Management reviews

#### Technical requirements:

- Personnel
- Accommodation and environmental conditions
- Test/calibration methods and method **validation**
- Equipment
- Measurement **traceability**
- Sampling
- Handling of test/calibration items
- **Assuring the quality** of the results
- Reporting the results

*THIS STANDARD PROVIDES RECOMMENDATIONS FOR:*

- *COMPETENCE FOR CALIBRATION AND TESTS*
- *METHOD VALIDATION*
- *TRACEABILITY AND UNCERTAINTY*

### 1.9.2.2 GENERAL REQUIREMENTS (ISO/IEC 17025:2005)

A QMS complying to the requirements of this standard will also meet the principles of ISO 9001.

This standard incorporates the requirements to prove the competence to carry out **tests** and calibrations (including sampling), and to generate technically valid data.

The specific requirements to ensure measurement **traceability**, method **validation** and estimation of the **uncertainty** of the provided results are emphasized.

### 1.9.2.3 SELECTION OF TEST/CALIBRATION METHODS

The laboratory shall use appropriate methods and procedures for all tests/calibrations within its scope. These include sampling, handling, transport, storage and preparation of the items to be tested/calibrated.

**the provision of electrical calibration support...**

... is often performed as secondary calibrations. A secondary calibration means that the results from a measuring device (or source) of unknown accuracy, are compared with those provided by a device whose accuracy is known. This device is universally accepted as "reference" and traceable to international standards. Calibration process records any deviations from this reference and corrects it when necessary.

When the customer does not specify the method to be used, the laboratory shall select methods that have been published in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts and journals, or as specified by the manufacturer of the equipment.

**1.9.2.4 METHOD VALIDATION**

The laboratory shall validate non-standard methods, laboratory developed methods and standard methods used outside their intended scope, and amplifications and modifications of standard methods, to confirm that the methods are fit for the intended use.

*CALIBRATION INSTRUCTIONS PURCHASED FROM MANUFACTURER OF CALIBRATION DEVICES SHALL BE VERIFIED, AT LEAST ON FIRST IMPLEMENTATION IN THE PRACTICE.*

The techniques used for the determination of the performance of a method should be one or a combination of:

- calibration using standards or reference materials.
- comparison with results achieved with other methods.
- inter-laboratory comparisons.
- systematic assessment of the factors influencing the results.
- assessment of the uncertainty of the results.

**1.9.2.5 EVALUATION OF THE CHARACTERISTICS OF PERFORMANCE OF A METHOD**

The main characteristics of performance of the method that shall be assessed during method validation are:

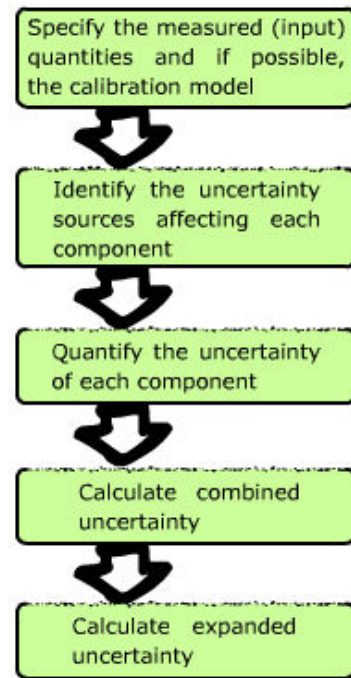
- selectivity of the method
- linearity, when applicable
- sensitivity
- reproducibility of the results
- trueness of the results
- uncertainty of the results
- detection limits
- robustness against external influences and/or interferences.

**The validation of an electrical calibration instruction** shall comprise the definition of its scope, the assessment of the characteristics of performance (precision and trueness), the assessment of the uncertainty and a declaration of validity.

#### 1.9.2.6 UNCERTAINTY ESTIMATION CHART

A calibration or testing laboratory shall have and apply a documented procedure to estimate the uncertainty of the measurements or calculated results derived from such measurements.

When the nature of the method may preclude rigorous, metrological and statistically valid estimation of uncertainty, the laboratory shall identify all the components of uncertainty and to make a reasonable estimation following the steps shown in the chart shown below.



#### 1.9.2.7 MEASUREMENT TRACEABILITY

All equipment used for tests/calibrations, including those for subsidiary measurements having effect for the validity of the results, shall be calibrated prior to use. The laboratory shall have an established programme and a procedure for equipment calibration.

Traceability of the measurement standards and measuring instruments to the International System of Units (SI) is established by means of an unbroken chain of calibrations or comparisons linking them to relevant primary standards of the SI units of measurements.

*WHEN USING EXTERNAL CALIBRATION SERVICES, TRACEABILITY OF THE RESULTS SHALL BE ASSURED BY THE USE OF CALIBRATION SERVICES FROM LABORATORIES THAT CAN DEMONSTRATE COMPETENCE, MEASUREMENT CAPABILITY AND TRACEABILITY.*

*CALIBRATIONS THAT CAN NOT BE MADE STRICTLY IN SI UNITS SHALL PROVIDE CONFIDENCE IN MEASUREMENTS BY ESTABLISHING TRACEABILITY TO APPROPRIATE MEASUREMENT STANDARDS (CERTIFIED REFERENCE MATERIALS, SPECIFIED METHODS OR STANDARDS)*

#### 1.9.2.8 SUMMARY ON ISO/IEC 17025

You must have learned that ISO/IEC 17025:2005 provides recommendations to ensure the quality and traceability of electrical calibrations, via:

- method validation
- traceability
- estimation of the uncertainty of the provided results.

### 1.9.3 QUALITY MANAGEMENT IN ELECTRONICS: ISO STANDARDS APPLICABILITY

How can we design a QMS aimed to ensure the quality of electronic services provision? Which recommendations and instructions shall be taking into account as to make such QMS compliant to ISO 9000 standard series requirements?

- We shall follow the ISO 9000:2005 principles, using this standard terms and definitions.
- Meeting customer requirements is not an easy task in electronic repair/maintenance services, but...

ISO 9001:2000 provides recommendations that are extremely useful for the organization of the work, if...

- the services are designed to meet customer needs (customer focus)
- the work is organized as a process
- resources are efficiently managed
- procedures and records are maintained
- the quality of the work is monitored and
- actions are addressed to ensure continual improvement.

ISO/IEC 17025:2005 provides recommendations to ensure the quality and traceability of electrical calibrations.