1 INTRODUCTION TO QUALITY MANAGEMENT

This section will introduce you to the basic concepts and definitions in Quality Management applied to XRF. 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 general and specific 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 of XRF. The following section will guide you to identify simple actions aimed to ensure the quality of your work in XRF.

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.

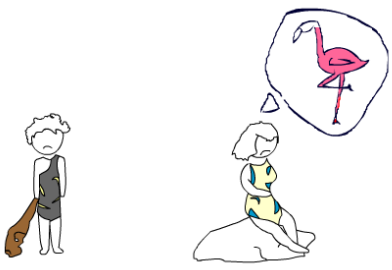
To be really efficient and effective, your XRF Laboratory can manage its way of doing things by systemizing it, even when you do not perform a routine work. This ensures that nothing important in your XRF practice is left out and that everyone is clear about who is responsible for doing what, when, how, why and where.

Success can result from implementing and maintaining a management system in the XRF Laboratory, 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

The earliest definition of quality probably occurs in early times...



Since then, there have been a lot of misunderstandings in between
'what I had in mind' and 'what my customer had in mind'

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.

1.3.1 THE DEFINITION OF QUALITY APPLIED TO ANALYTICAL LABORATORIES

In the case of a laboratory providing analytical results, quality can be understood as the degree of compliance to the requirements of the customers. Therefore, the customer shall be requested to be specific in regard to:

- what type of material has been brought for analysis? The type of material (sample matrix) will allow to define the type of interferences that can be expected, the expected detection limits (since there will be more or less attenuation/scatter/enhancement effects), the availability of calibration or not, among other figures of performance.
- which elements need to be analyzed? The list of required elements will address the analyst into the selection of proper excitation/measurement conditions.
- what is the expected concentration/weight fraction of the elements in the sample? The stated concentration/weight fraction allows to select a method with sufficient sensitivity and detection limits.
- what is the expected uncertainty for the results? One of the main figures to define the fitness of a given method for the purpose the results are expected.

1.4 ISO 9000:2005. LOOKING FOR A CONSENSUS

The ISO 9000 family of standards represents an international consensus on good quality management practices. It consists of standards and guidelines relating to quality management systems and related supporting standards.

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

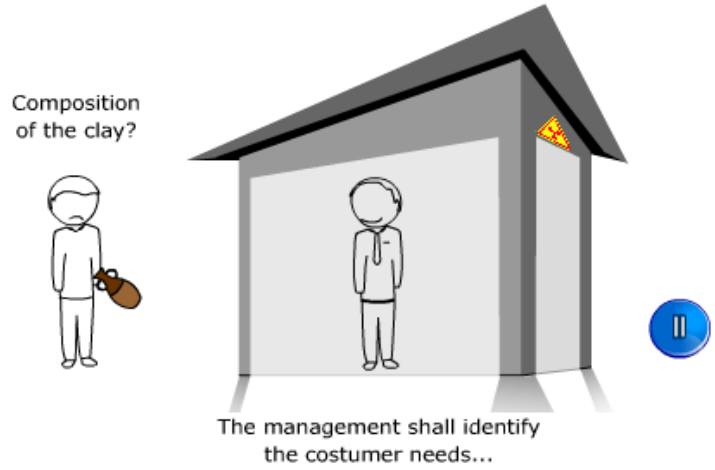
- **Terms and definitions**

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 CUSTOMER IS ALWAYS RIGHT!

1.6.2 QM KEY PRINCIPLES: LEADERSHIP

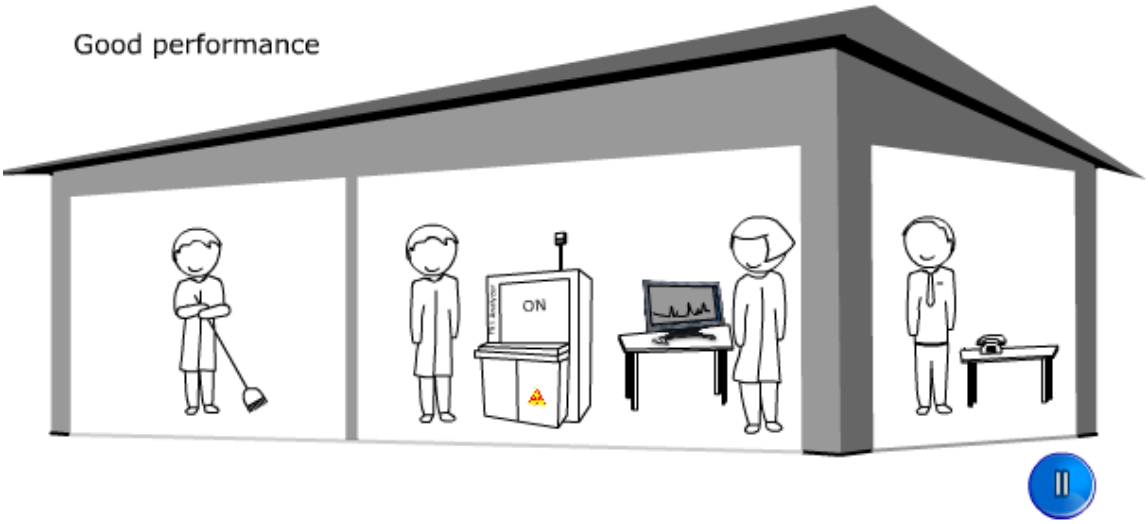
Leaders establish unity of purpose and direction of the organization.

- 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.

TO BECOME A REAL LEADER, NOT JUST THE BOSS!

1.6.3 QM KEY PRINCIPLES: PEOPLE INVOLVEMENT

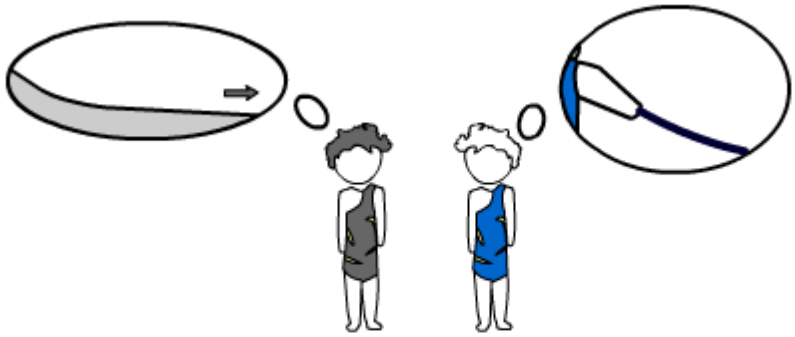
People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.



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

1.6.4 QM KEY PRINCIPLES: PROCESS APPROACH

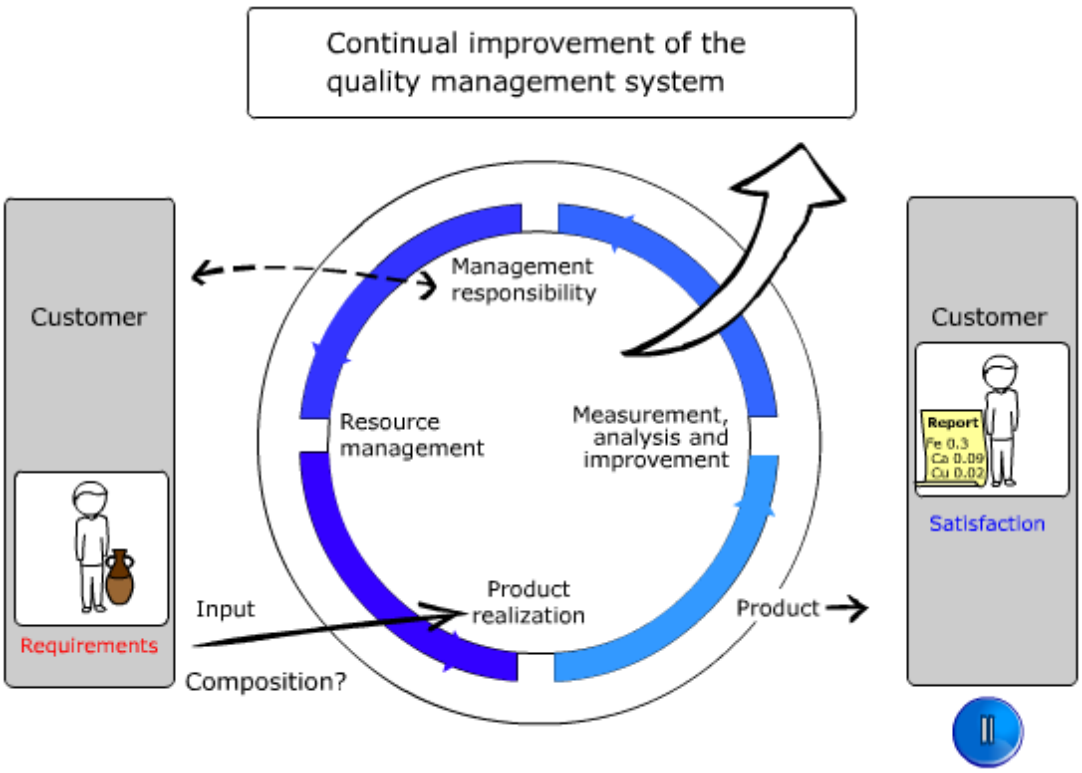
A desired result is achieved more efficiently when activities and related resources are managed as a **process**.



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

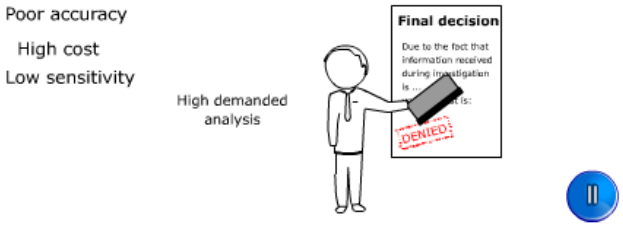
Continual improvement of the organization's overall performance should be a permanent objective.

Continual improvement of organization performance leads to better services.

WE ARE GOOD… BUT WE CAN BE EVEN BETTER!

1.6.7 QM KEY PRINCIPLES: FACTUAL APPROACH TO DECISION MAKING

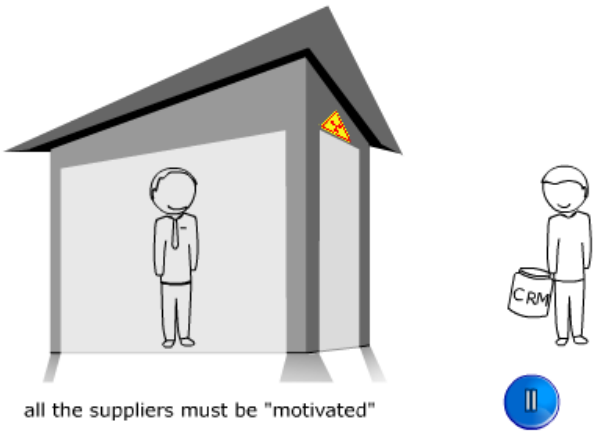
Effective decisions are based on the analysis of data and information.



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

1.6.8 QM KEY PRINCIPLES: MUTUALLY BENEFICIAL SUPPLIER RELATIONSHIPS

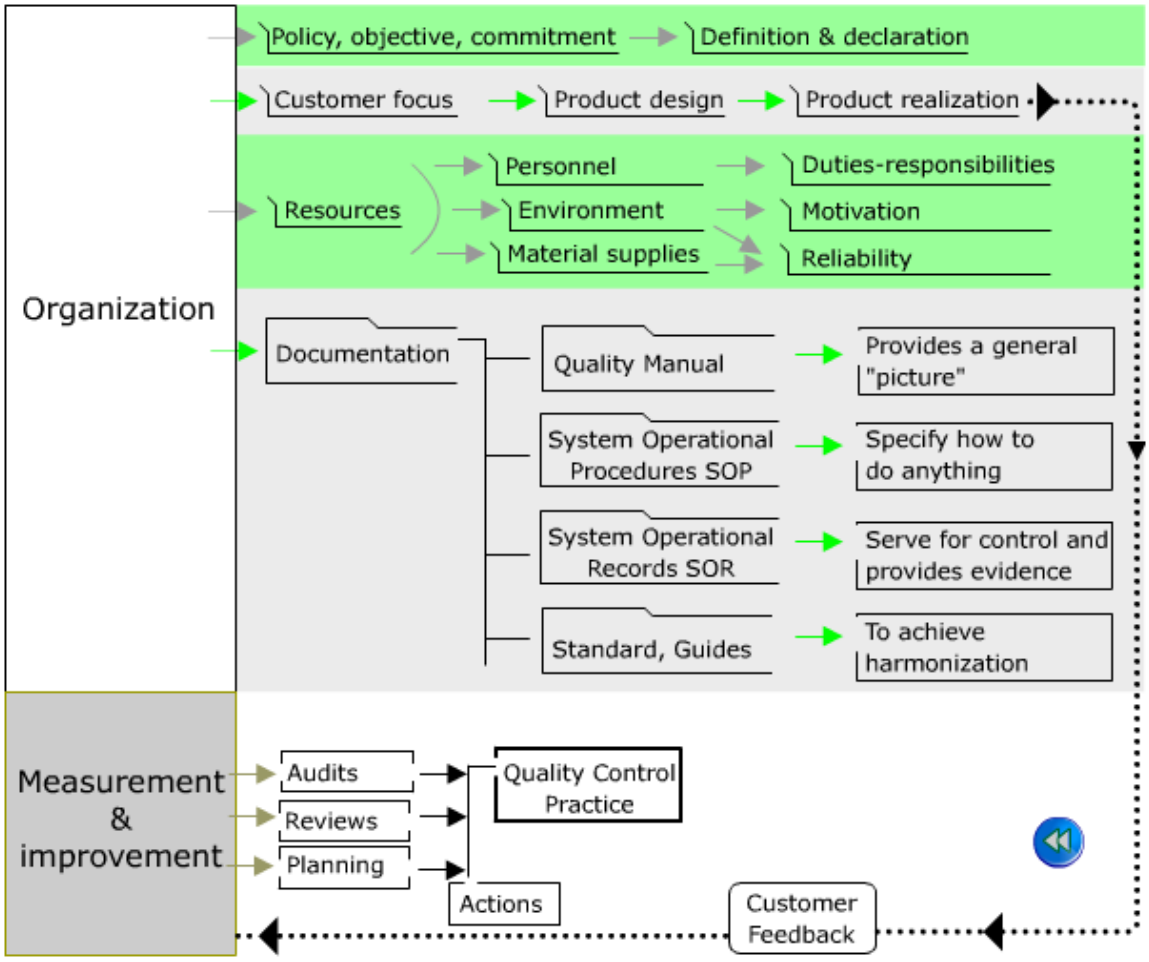
An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.



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

ISO 9001:2000 is an international standard that gives requirements for an organization's Quality Management System (QMS). It is the only standard in the ISO 9000 family that can be used for the purpose of conformity assessment.

The objective of ISO 9001:2000 is to provide a set of requirements that, if effectively implemented, will provide you with confidence that your XRF Laboratory can consistently provide analytical services that:

- Meet customer needs and expectations and
- Comply with applicable regulations.

The requirements cover a wide range of topics, including top management commitment to quality, customer focus, adequacy of its resources, employee competence, process management (for production, service delivery and relevant administrative and support processes), quality planning, product design, review of incoming orders, purchasing, monitoring and measurement of its processes and products, calibration of measuring equipment, processes to resolve customer complaints, corrective/preventive actions and a requirement to drive continual improvement of the QMS. Last but not least, there is a requirement to monitor customer perceptions about the quality of the analytical services you provide.

ISO 9001:2000 does not specify requirements for the analytical services you are selling. That is up to your costumers to define, by making clear their own needs and expectations for the analytical service. As an example, if you provide XRF instruments and consumables, they might refer to product specifications, drawings, national or international product standards, supplier's catalogues or other documents as appropriate.

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

1.9.2 Introduction to the ISO/IEC 17025:2005

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

ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

It is applicable to all organizations performing tests and/or calibrations, as your XRF Laboratory do. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration is part of the process of inspection and product certification.

ISO/IEC 17025:2005 is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When an XRF laboratory does not undertake one or more of the activities covered by ISO/IEC 17025:2005, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

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

ISO/IEC 17025:2005 is for use by XRF laboratories in developing their management system for quality, administrative and technical operations. XRF laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. Accreditation bodies that recognize the competence of testing and calibration laboratories should use this International Standard as the basis for their accreditation.

Compliance with regulatory and safety requirements on the operation of laboratories is not covered by ISO/IEC 17025:2005.

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

A TECHNICAL CORRIGENDUM TO ISO/IEC 17025:2005 WAS APPROVED IN 2006.

1.10 Applicability in Analytical Laboratories

Since a quality assurance programme involves more work, increased costs and additional paperwork, one may be tempted to ask: What are the benefits? Is it worth the cost?

The main benefit of a quality assurance programme in an XRF Laboratory is that it provides assurance to the laboratory itself, as well as those who rely on its services, that it is operating under control and that it is producing data of consistent and proven quality.

On the question of costs you should consider the following situation. Suppose you are doing an XRF analysis that cost $100 to perform and, for whatever reason, you get a wrong result. This means you have just spent $100 to obtain perfectly useless information. Furthermore, costly decisions may be made on the basis of this erroneous information.

Application of quality assurance to routine XRF analytical testing is fairly well established with widespread availability of general and specific guidance, both on general principles and in support of quality standard and accreditation/certification schemes.

The application to non-routine work is less straightforward and available guidance results mainly from "adapting" more "flexible" standards. Nevertheless, in any XRF Laboratory it is possible to address quality at several levels. The same elements of technical Quality Assurance are applicable to non-routine measurements and Research & Development as are applied to routine work. However, the approach taken to their implementation must be different.