1 INTRODUCTION TO QUALITY MANAGEMENT

This section will provide you with examples on how to implement actions in your Quality Management program to pursue the fulfilment of the ISO 17025 requirements.

Some examples are provided for illustration on how to implement actions for the particular case of XRF analytical 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.

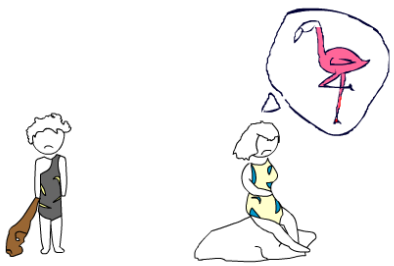
To be really efficient and effective, your XRF Laboratory can manage its way of doing things by systemizing it, even when you do not perform a routine work. This ensures that nothing important in your XRF practice is left out and that everyone is clear about who is responsible for doing what, when, how,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

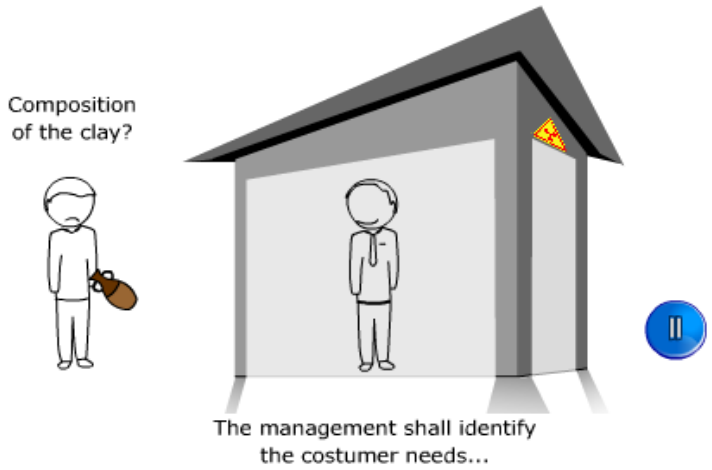
- **Fundamentals:**
  - Rationale
  - Requirements for QMS
  - Requirements for products
  - QMS approach
  - Process approach
  - Quality policy and quality objectives
  - Role of top management
  - Documentation
  - Evaluation of QMS
  - Continual improvement
  - Role of statistical techniques
- **Terms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

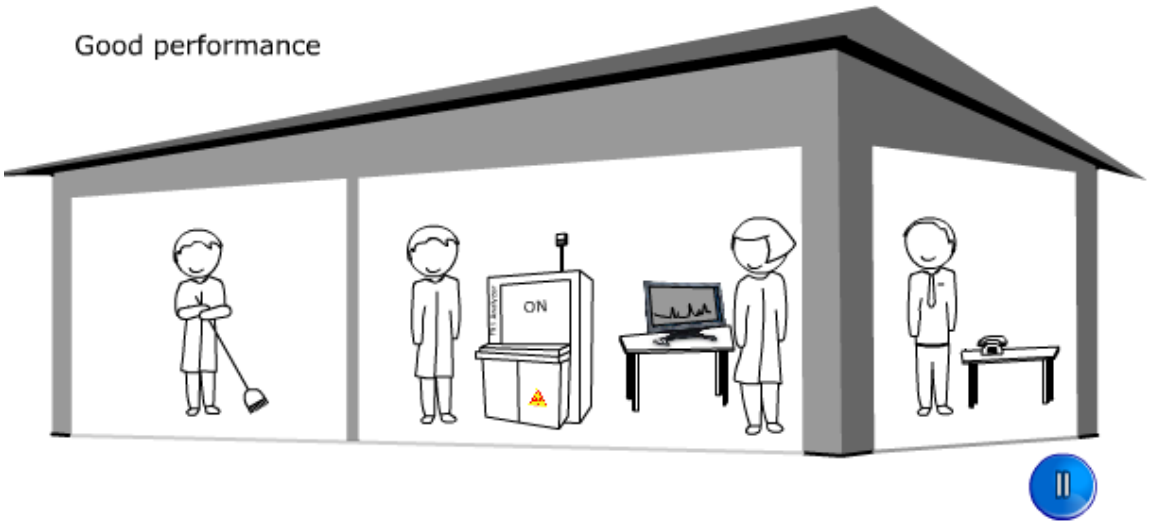
Leaders establish unity of purpose and direction of the organization.

- 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

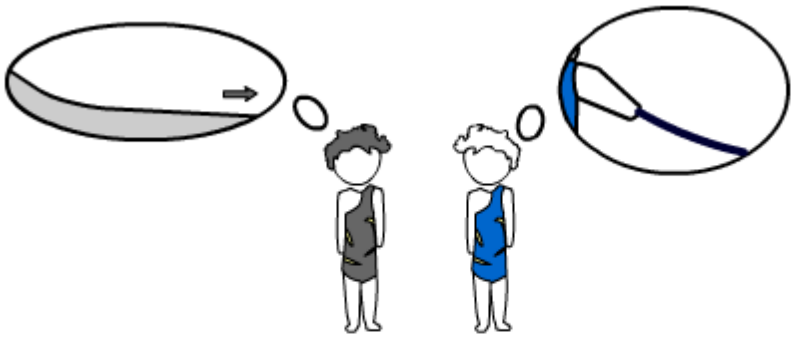
People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.



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

1.6.4 QM KEY PRINCIPLES: PROCESS APPROACH

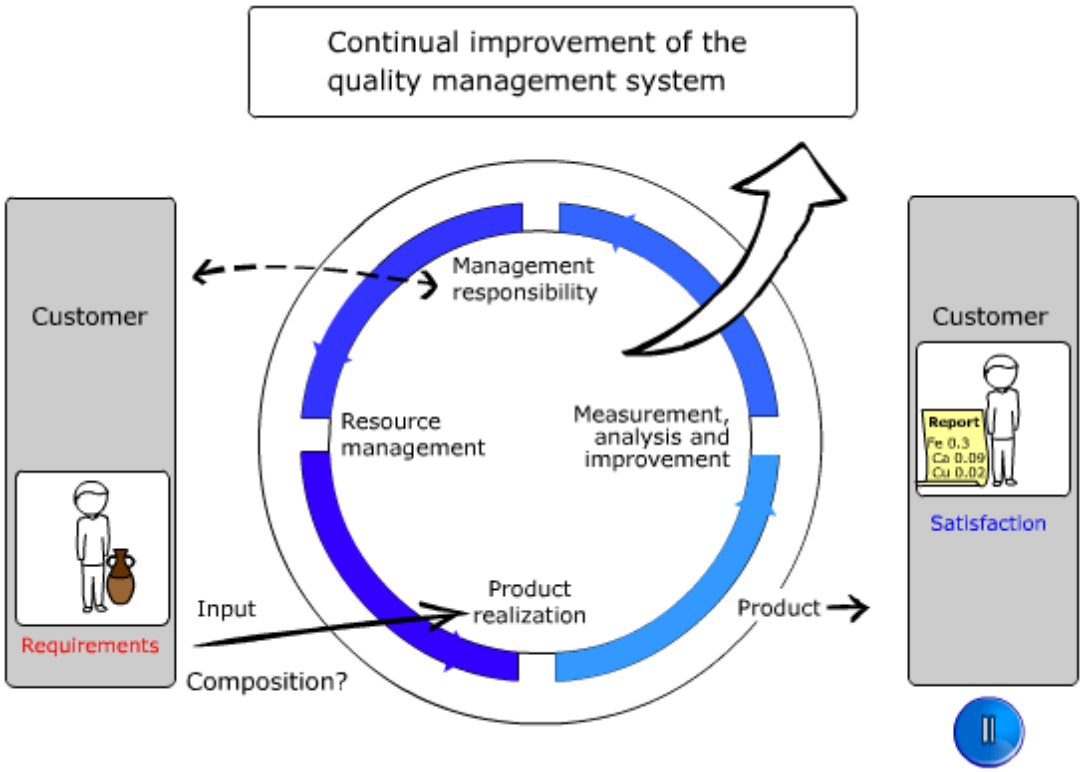
A desired result is achieved more efficiently when activities and related resources are managed as a **process**.



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.

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

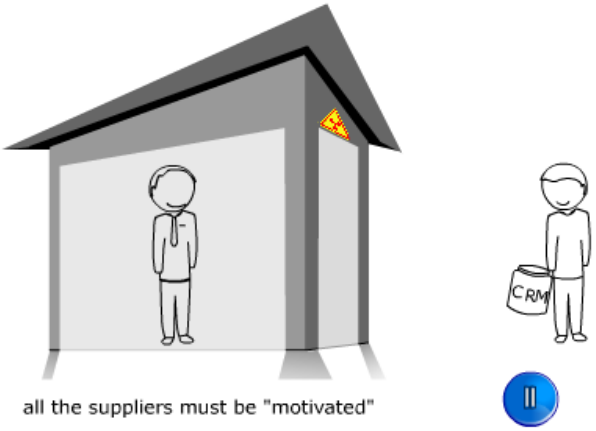
1.6.7 QM KEY PRINCIPLES: FACTUAL APPROACH TO DECISION MAKING

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

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

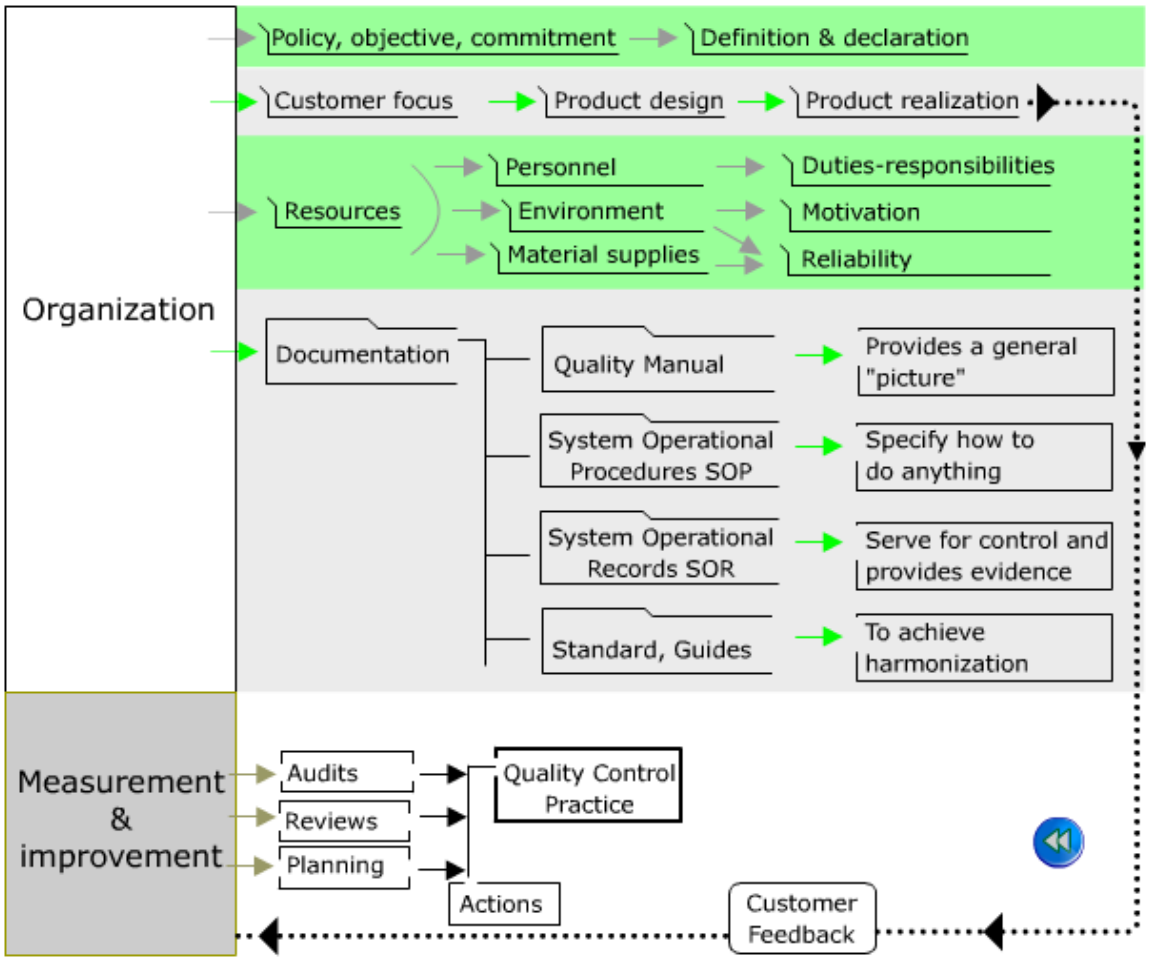
1.6.8 QM KEY PRINCIPLES: MUTUALLY BENEFICIAL SUPPLIER RELATIONSHIPS

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



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.

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.

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.

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.

Although one of the most advantageous features of XRF analysis is its high versatility, a careful selection of a particular method implementation shall be made for each application. One shall be aware that XRF is a phenomenon (not a method in itself), based on which a large and diverse groups of analytical solutions have been implemented. While selecting a particular implementation of XRF, you shall be aware of:

- what type of material needs to be analyzed?
- which elements need to be determined?
- what is the expected concentration / weight fraction of the elements in the sample?
- what is the expected uncertainty for the results?

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.

In XRF spectrometry is common to use in-house developed methods. Method validation is realized by carrying out measurements on appropriate reference material or comparison with results of reliable independent methods. This is due to the fact that result values in certified reference materials are of a higher metrological level than individual laboratory results. Matrix reference materials are the most commonly used.

- *Method validation* is a process of verifying that a method is fit for purpose, this means fit for solving a particular analytical problem.

- *Method validation* is a process of establishing the performance characteristics and limitations of a method and the identification of the influences that may change these characteristics and to what extent. Which analytes can it determine in which matrices in the presence of which interferences?

- *A collaborative study of a method* involves practical testing of the written version of the method, in its specific style and format, by a number of laboratories on identical materials.

- *In-house method validation* is not a standardized term. It is used in this context to denote the method validation process carried out by one laboratory.
- *Single-laboratory method validation*: This term is used when the method is developed and validated in the same laboratory

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:

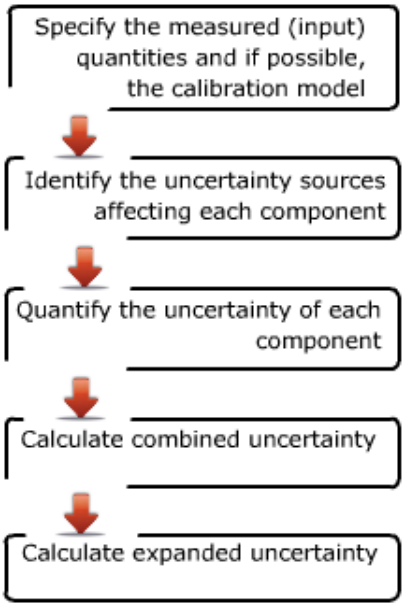
- selectivity of the method
- linearity, when applicable
- sensitivity
- reproducibility of the results
- trueness of the results
- uncertainty of the results
- detection limits
- robustness against external influences and/or interferences.

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.

Since EDXRF has different quantitative approach or methodologies for the determination of element concentration, the uncertainty budget must be carried out for the specific quantitative method used.



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)

Even though traceability to an SI unit is the desired goal, direct linkage is not easy and is not the usual line of approach in XRF analysis. The SI unit is rather linked indirectly to a measurement procedure. For this purpose, the measurand needs to be defined as a function of the measurement parameters. This provides the working equation that models the experimental measurement and conditions, and ascribe results to the measurand. Subsequently, the correctness of the working equation (method specification) in representing the real situation is assessed through validation, and uncertainties evaluated.

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 Analytical Laboratories: ISO Standards applicability

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.

Quality assurance ensures that most results are correct and that incorrect results are detected and corrected so that only useful information is produced.

1. How can we design a QMS aimed to ensure the quality of measurements in analytical laboratories? Which recommendations and instructions shall be taking into account as to make such QMS compliant to ISO 9000 standard series requirements?

    a. We shall follow the ISO 9000:2005 principles, using this standard terms and definitions.

    b. Meeting customer requirements is not an easy task in analytical laboratories, but...

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

    a. the services are designed to meet customer needs (customer focus)

    b. the work is organized as a process

    c. resources are efficiently managed

    d. procedures and records are maintained

    e. the quality of the work is monitored and

    f. actions are addressed to ensure continual improvement

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