COURSE HANDBOOK

UNDERSTANDING ISO/IEC 17025:2017

MOTIVA Training

Motivating Best Practice in Lab QMS

Rev 6

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Introduction

Course Development

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Course Description

This course is aimed at laboratory staff:

- Who participate in the operation of the laboratory quality system – in the conduct of their testing, calibration or laboratory support activities
- Who participate in the management of the laboratory quality system
- Who participate in the management of the laboratory.

Laboratories are accredited in order to meet regulator and client competence requirements. This course will provide information to laboratory staff seeking ways to better understand the requirements behind ISO/IEC 17025-the standard used in laboratories.

Course Learning Objectives

The course will assist you to:

- **understand** the principles behind ISO/IEC 17025;
- **understand** the main technical requirements of ISO/IEC 17025;
- **identify** the requirements for reporting results;
- **identify** appropriate methods for demonstrating continuing competence of personnel;
- **understand** the broad concept of measurement traceability,
- **identify** the laboratory accreditation requirements for traceability,
- **understand** how a laboratory can structure its quality system to meet organizational goals
- **identify** laboratory approaches in the documenting a quality system;
- **identify** the approaches to documenting capacity and competence.
- **identify** laboratory approaches in identifying NCs and OFIs;
- **understand** the concepts of corrective and preventive action;
- **appreciate** the requirements for internal audit and management review;
- **understand** how to close out and follow up findings from all sources.

Completing the Course

The course material is broken down into chapters. Within each chapter, specific objectives are listed as well as instructions on how to complete each chapter. Directions are provided to guide you through the readings, other reference materials, and work to be completed.

Course Content

The syllabus for this course is as follows.

<u>Chapter 1 – Background and Principles</u>

- Introduction to the principles behind ISO/IEC 17025
- Emphasis on competence, instead of simple conformance
- The components of a laboratory quality system (people, documents, records)

<u>Chapter 2 – Basic Technical Requirements</u>

- Staff training requirements and records
- Accommodation requirements
- Equipment requirements

- Sampling in support of testing and calibration
- Handling samples and chain of custody
- Establishing the "second set of eyes" – quality control / quality assurance
- Reporting the results
- Interpretations and opinions

Chapter 3 – Technical Measurement Requirements

- Establishing fitness for purpose of methods and procedures
- Traceability requirements
- Estimating and reporting uncertainties associated with measurements
- Demonstrating traceability of measurement
- The traceability chain and its components
- What to look for in a calibration service provider
- Using measurement uncertainty to establish calibration requirements

Chapter 4 – Basic Management System Requirements

- Basic management systems
- Document control, including the use of electronic support to the laboratory.
- Establishing control of records
- Establishing "Capacity"
- Acquiring "Competence"
- Feedback as a management tool.

Chapter 5 – Continual Improvement Requirements

- Continual Improvement definitions and concepts
- Identifying NCs and OFIs
- Implementing corrective and preventive action

Chapter 6 – Monitoring and Measuring a Laboratory Quality System

- The elements of the periodic internal audit (what needs to be audited)
- The elements of the management review (what needs to be reviewed)
- The conduct of audits and their findings
- The conduct of management reviews and their decisions
- Tracking internal audit findings and management review decisions
- Close out and follow up

Course Grading

The quiz is at the end of the course and will allow you to measure your acquired knowledge of laboratory accreditation. Participant evaluation will be based on the result of the quiz. 70% is required in order to pass this course.

All participants are eligible to receive a Certificate of Participation. Participants who wish to receive a Certificate of Successful Completion must do two things:

- Answer the discussion activity questions in each chapter, and
- Pass the quiz at the end of the course.

Chapter 1 – Background and Principles

1.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** the principles behind ISO/IEC 17025;
- **appreciate** the rationale behind laboratory accreditation, and
- **understand** how a laboratory can structure its quality system to meet organizational goals.

1.2 Completing the Chapter

Discussion Activity 1.1

Which of the following benefits accrue to a laboratory that has implemented a 17025-conformant quality system:

a. fewer errors
b. regulatory approval
c. fewer people
d. greater measurement precision
e. more profit
f. more consistency of results
g. access to wider market

Discussion Activity 1.2

What are the characteristics of a laboratory that a regulator desires before they make use of the results of that laboratory for either policy development or regulatory enforcement?

a. really good advertising
b. ISO 9001 certification
c. consistent results
d. political relationship to ministers
e. accreditation to 17025
f. large and modern lab facilities

Discussion Activity 1.3

Which of the following are not Principle(s) behind ISO/IEC 17025?

a. Capacity
b. Exercise of Responsibility
c. Scientific Method
d. Systematic Approach
e. Objectivity of Results
f. Customer Focus
g. Impartiality of Conduct
h. Traceability of Measurement
i. Mutually Beneficial Supplier Relationships
j. Repeatability of Test
k. Leadership
l. Transparency of Process

Discussion Activity 1.4

What are the choices available for a laboratory to write its Quality Manual?

a. Use the numbering system and clause structure from ISO/IEC 17025 to write the Quality Manual
b. Use the Principles behind ISO 9000 to write the Quality Manual
c. Create and use laboratory/corporate/Ministry objectives to write the Quality Manual
d. Use the wording in ISO/IEC 17025, clause 4.2.2 to write the Quality Manual
e. Use the Principles behind ISO/IEC 17025 to write the Quality Manual

1.3 Laboratories and Quality Considerations

1.3.1 Driving Forces

There are many reasons to implement practices that help us do our jobs better, whether we work in a laboratory or other organization. If the reason to implement this type of practice is to enforce a very stringent improvement under law, then a regime of constant inspection may be what is needed to help us do what the law requires. On the other hand, if we are called upon to continuously demonstrate competence, implementing and operating a laboratory quality system that conforms to ISO/IEC 17025 may be the best approach. The approach selected depends entirely on the reason for the needed improvement.

Laboratory quality systems, which conform to ISO/IEC 17025, have the primary aim of helping the laboratory produce valid results, and to show others that it is capable of doing so. This is the concept of "competence." It may be that a regulatory authority has "required" this demonstration of competence, but that is beyond the scope of the standard, other than the clause that calls upon the laboratory to "obey the laws of the land."

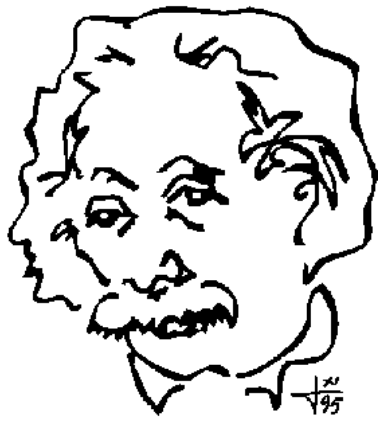
Unlike a manufacturing facility, where the needs of the customer may be balanced against the ability of the organization to meet them, a laboratory must also meet the needs of the science that underlies its test results. While a manufacturing facility can be registered to the world's best "model-for-excellence" standard (ISO 9001:2008) in order to instil stakeholder confidence in its work, a laboratory gains the trust of its stakeholders (including regulators) through demonstrated competence in the science only.

The most common reasons behind the implementation of a laboratory quality system are:

- A desire to improve the consistency (and/or quality) of lab results
- A desire to demonstrate competence
- Specified by laboratory clients (market) or a regulatory agency

1.3.2 Consistency

If perfection in a testing laboratory were to be described, and perfection was based on the principles behind ISO/IEC 17025, the description would probably look like this:



"We can produce consistent results, day after day, within the ninety-five percent confidence region, day after day."

Drawing by Iutta Waloschek.

From the website of the University of St. Andrews, Scotland.

www-gap.dcs.st-and.ac.uk/~history/PictDisplay/Einstein.html

This attitude, the inherent dedication to the science and the apparent lack of flash and colour in the person making the statement are the very characteristics that engender trust in the work of a laboratory.

From the requirements given in ISO/IEC 17025, and the principles behind the standard, this is a PERFECT lab – and 5% of their results may still be outliers.

Remember that ISO/IEC 17025 is only concerned with competence, not the provision of business solutions. It seeks to provide laboratories with a system to help it achieve this state of "perfection" characterised by consistency and competence.

These are the characteristics that engender trust in the work of a scientist,

- Their apparent dedication to the science
- Their concentration on consistency and competence,
- Their understanding that there is no such thing as an "absolute result"

1.3.3 Quality of Lab Results

ISO 9000 defines *quality* as the "*degree to which a set of inherent characteristics* (of a product or process) *fulfils requirements*".

Commonly, this concept is often referred to as "being fit for purpose." The easy part to understand is that the concept of "quality" is very dependent on the needs of the persons or organization that are measuring the "thing" for quality. For example, does plastic water bottle have more, or less, quality in it, than ceramic coffee mug? The answer is, "it depends."

If the need for the use of the vessel for holding liquid is described as:

"Taking it with me while hiking through the forest."

then the water bottle has at least as much quality in it as the coffee mug. If the need for the use of it is described as:

"*Holding comforting hot coffee or chocolate at my campsite.*"

then it is likely that the coffee mug will be substantially more fit for purpose - hands down.

The same approach applies to the work done by a laboratory. *Fitness for purpose* is defined by the laboratory in considering the needs of the science, the client and any regulators having a stake in the test results. *Quality work* is work that meets all of these needs.

For a laboratory quality system, "Quality" **does not always** imply "High Quality" or going beyond the expectation of value, etc.

Within a laboratory, "Quality" **may imply** lower cost for expected result or value added over and above what was desired or what was purchased.

For the lab staff, and the users of the products (data) of the lab, "Quality" **always** implies predictability and consistency or meeting expectations

1.3.4 Competence in a Laboratory

ISO/IEC 17024 defines *competence* as "*demonstrated ability to apply skills and knowledge*".

Unless the competence of a laboratory is "judged", its demonstration of conformance to any standard does not give anyone any confidence that the people in that laboratory know what they are doing. Laboratory staff can follow procedures without understanding the science behind a test, and this would allow them to conform to a stated specification – but they are not necessarily "competent."

The standard against which laboratories are accredited (formally recognised for their competence) is ISO/IEC 17025. It is entitled – *General Requirements for the Competence of Testing and Calibration Laboratories.* The standard is about one thing only – Competence.

"Competence" means that the persons in a laboratory have specific knowledge and skills directly related to the science underlying their testing procedures. "Competence" means that the staff in a laboratory can demonstrate this specific knowledge. "Competence" means that the procedures conform to the requirements of the science. Only someone else who has the same level of knowledge and skills within that science can determine "competence".

Demonstrated conformance to ISO/IEC 17025 includes a rigorous "*demonstration of competence.*" The demonstration of competence will show that the laboratory has the people, with the skills and knowledge,

the environment with the facilities and equipment, the quality control and the procedures that are required to produce valid results. See principle #1, "Capacity" in *T06 - The Principles behind ISO/IEC 17025* (*http://motiva-training.com/images/stories/T06_-_17025_Principles.pdf*).

Note that ISO/IEC 17025 is not a perfect document. Its revisions were created and written by imperfect people who made mistakes in creating them. For example, the standard emphasises the value of ISO 9001, when it is very well understood that ISO 9001 is not an appropriate standard to use by a laboratory to support their demonstration of competence in the production of technically valid results. The reason we wrote it this way was to ensure that laboratory clients requiring conformance to ISO 9001 (as a pre-requisite to getting business) would be able to claim equivalence, simply by being accredited to ISO/IEC 17025. Today accreditation is often seen as "more appropriate" than simple certification. See the "Peace Treaty" at http://motiva-training.com/images/stories/17025_Joint_Communique.pdf.

A laboratory quality system which conforms to ISO/IEC 17025 can also be part of a larger quality system which conforms to ISO 9001. In other words, a company can have ONE quality system that conforms to BOTH standards.

A quality system based on ISO 9001:2008 is aimed at facilitating the organization's ability to produce conforming product or service. Who defines conforming?

- The organization itself
- The organization's clients
- A third-party document (test method, etc)

A quality system based on ISO/IEC 17025 is aimed at producing competent (valid) results. The **ONLY** authority for competence that can indicate whether the work was done competently is the third party test standard or method, which is governed by a consensus within the community of the science covered by the method.

1.3.5 Specification by a Client or a Regulatory Agency.

Nations and their citizens rely on regulatory agencies to manage public sector efforts to provide for the health, welfare, and safety of citizens in many areas. This includes product safety, drinking water, foods, and the environment.

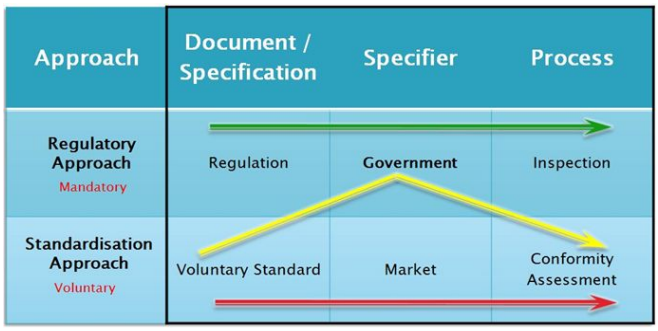
Citizens normally rely on the food safety regulators to ensure that the laboratories that test foods are competent enough to determine when something is acceptable or not. In many nations, the regulators require that the laboratories are accredited to ISO/IEC 17025 before they will allow them to conduct any tests.

Many nations also rely on their environmental authorities to ensure that laboratories that test for environmental parameters also meet similar guidelines.

1.3.6 From Specification to Competence

How do regulatory agencies normally participate in this effort? See the chart below. It shows the differences between the two main approaches used by regulators to execute their primary responsibility, "*protecting the health, welfare and safety"* of citizens within their jurisdiction.

Standards vs Regulations



The green line at the top shows how a government develops a regulation, then specifies its use, and finally enforces it through inspection. Examples include national regulatory agencies in workplace health and safety or in food and drug administration regulations.

The red line at the bottom is an example of how ISO 9001 and ISO/IEC 17025 are normally delivered without any regulator specification – "by the market, from the market, and

for the market". These two standards were developed from within their own communities. Both were developed internationally and included the input of their clients and other stakeholders, including governments. They are delivered using voluntary conformity assessment techniques.

The yellow line in the middle represents how a government can specify a voluntary standard. ISO/IEC 17025 and relevant guidelines are delivered today to laboratories, which, if they wish to do business in some specific fields, must meet regulatory requirements for accreditation. These are now part of regulatory tool kits in the protection of the health, welfare and safety of citizens of many nations around the world.

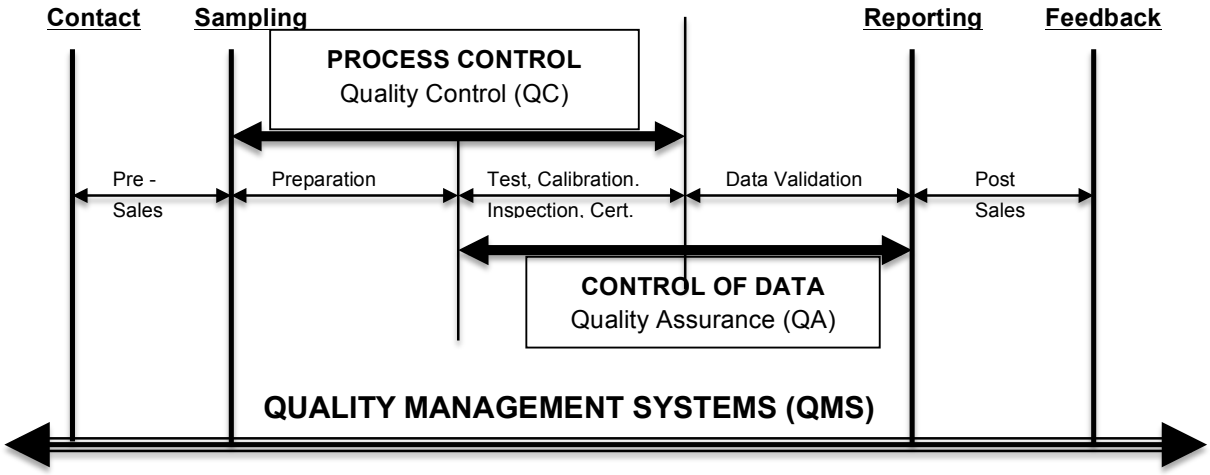
Each of the three components of either type of approach involves:

- writing something that can be used to determine acceptable behaviour (standard or regulation),
- specifying the necessity for this behaviour (the market or some legislation), and
- determining how to evaluate performance against the specification (inspection or conformity assessment).

1.4 Laboratory Quality Systems

1.4.1 Scope of Lab Operations

Laboratories conduct tests or calibrations. Both of these activities are defined as conformity assessment activities within ISO definitions. For a testing laboratory, the normal scope of operations of the laboratory can be depicted as follows.



Includes all functions that influence the validity of technical results

- All business operations functions
- All management and administrative functions
- All finance functions
- All HR functions
- All purchasing and contract review functions
- All marketing and communications functions
- All maintenance functions

Quality control activities are aimed at ensuring the processes continue to be fit for purpose. Quality assurance activities are aimed at ensuring the results of the processes continue to be fit for purpose. A quality management system covers both of these disciplines and the other supporting procedures used to ensure that a laboratory produces technically valid results.

1.4.2 Terminology

Most of the terms used in this training are provided from the standard international definitions for these terms. They are drawn from the following documents.

- ISO/IEC 17000 – *Conformity Assessment – General Vocabulary*,
- ISO/IEC 17011 – *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies,*
- JCGM 100: 2008 – *Evaluation of measurement data — Guide to the expression of uncertainty in measurement (GUM)*
- JCGM 200:2012 – *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*
- ISO/IEC 17024 – *General requirements for bodies operating certification schemes for persons*,
- ISO 9000 – *Quality Management Systems – Fundamentals and Vocabulary*

MOTIVA publishes the *MOTIVA 17025 Guide* a document that includes the definitions most relevant to accredited laboratories. It contains the following definitions.

Accreditation:

Third-party attestation that a conformity assessment body fulfils specified requirements and is competent to carry out specific conformity assessment tasks (ISO/IEC 17000, 2.4.6).

Formal recognition of the competence of a laboratory to carry out specific testing and calibration activities. Competence is demonstrated when the laboratory also demonstrates that it has: the people with the skills and knowledge; the environment with the facilities and equipment; the quality control, and the procedures required to produce technically-valid results.

Accuracy (or Measurement Accuracy):

Closeness of agreement between a measured quantity value and a true value of the measureand. [VIM, 2.13]

NOTES

- The concept ‘measurement accuracy’ is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.
- The term “measurement accuracy” should not be used for measurement trueness and the term measurement precision should not be used for ‘measurement accuracy’, which, however, is related to both these concepts.
- ‘Measurement accuracy’ is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measureand.

Assessment:

Examination of competence of a body, against specified requirements, by representatives of other bodies in, or candidates for, an agreement group (ISO/IEC 17000, 4.5). An assessment typically involves a determination of competence. Assessors assess competence in specific disciplines, in which they are technical experts.

Audit:

Systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled. (ISO/IEC 17000, 4.4)

Bias:

The difference between the expectation of the test results and an accepted reference value. (ISO 3534-1, 3.13).

Calibration:

Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication. [VIM 2.39]

NOTES

- A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.
- Calibration should not be confused with adjustment of a measuring system, often mistakenly called “self-calibration”, nor with verification of calibration.
- Often, the first step alone in the above definition is perceived as being calibration.

Calibration requires a comparison of measurements between two standards or measurement devices. It involves the competent propagation of uncertainties from the instrument or standard whose measured (and measurement) characteristics are already quantified and traceable (see traceability) to the SI.

Calibration of a Method:

Determination of the characteristics of results produced when using a specific method. Method calibration is part of Method Validation (See ISO/IEC 17025 clause 5.4.1). Method calibration procedures need to include, as appropriate:

- use of a reagent blank to establish a calibration baseline;
- use of equivalent standard/sample reagent background;
- use of an adequate number of standards;
- establishment of linearity and calculation of slope and/or RRF;
- use of a control standard to monitor calibration stability/accuracy;
- use of control charting; and,
- identification of calibration non-conformance.

Certification/Registration:

Third-party attestation related to products, processes, systems or persons.

- Certification of a management system is sometimes also called registration.
- Certification is applicable to all objects of conformity assessment except for conformity assessment bodies themselves, to which accreditation is applicable (ISO/IEC 17000, 5.5)

Certified Reference Material (CRM):

Reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceabilities, using valid procedures [VIM 5.14]

Competence:

Ability to apply knowledge and skills to achieve intended results. (ISO 9000, 3.10.4)

Note 1 to entry: Demonstrated competence is sometimes referred to as qualification.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

Complaint:

Expression of dissatisfaction, other than disputes and appeals, by any person or organization, to a person or body, relating to the activities of that person or body, where a response is expected. (ISO/IEC 17011, 3.9)

Conformity/Conformance:

Fulfillment of a requirement. (ISO 9000, 3.6.11)

Note 1 to entry: In English the word “conformance” is synonymous but deprecated. In French the word “compliance” is synonymous but deprecated.
Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Note 1 to entry.

Conformity Assessment:

Demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. (ISO/IEC 17000, 2.1)

Control Sample:

A sample used as a basis for comparison with test samples, and which undergoes sample processing identical to that carried out for test samples. Includes reference samples, method blanks, control samples (e.g., dilution water as used in toxicological testing) and control cultures (e.g., samples of known biological composition).

Control Standard:

A standard used as a basis for comparison with calibration standards, prepared independently from the calibration standards, and which undergoes sample processing identical to that carried out for the calibration standards. The term is synonymous to Working Measurement Standard. (VIM, 5.7)

Corrective Action:

Action to eliminate the cause of a [detected] nonconformity [or other undesirable situation] and to prevent recurrence. (ISO 9000, 3.12.2)

Note 1 to entry: There can be more than one cause for a nonconformity.
Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.
Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by adding Notes 1 and 2 to entry.

Correction:

Action to eliminate a detected nonconformity. (ISO 9000, 3.6.9)

Note 1 to entry: A correction can be made in advance of, in conjunction with or after a corrective action
Note 2 to entry: A correction can be, for example, rework or regrade.

Decision Rule:

Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

Holding Time:

Elapsed time between sample collection and either sample preparation or analysis, as appropriate.

Limit of Detection:

The limit of detection, expressed as a concentration (or amount), is derived from the smallest measure that can be detected by a single measurement with reasonable certainty for a given analytical procedure. [IUPAC 1975]

Limit of Quantitation:

The lower limit of concentration or amount of substance that must be present before a method is considered to provide quantitative results. By convention, LOQ = 10 x s, where s is the estimate of the standard deviation at the lowest level of measurement. (NIST 260-100).

Method Blank:

Blank which undergoes sample processing identical to that carried out for the test samples. Blank results are used to assess contamination and/or provide background correction to analyte concentrations.

Measurement Standard:

Realization of the definition of a given quantity, with stated quantity value and associated measurement uncertainty, used as a reference. (VIM, 5.1)

Nonconformity / Non conformance (NC):

Non-fulfilment of a requirement. (ISO 9000, 3.6.9)

Note 1 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

Potential Nonconformity / Potential Non conformance (PNC):

Possible and potential non-fulfilment of a requirement. (derived from 3.6.9 of ISO 9000)

Precision or Measurement Precision:

Closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions [VIM 2.15]

NOTES

- Measurement precision is usually expressed numerically by measures of imprecision, such as standard deviation, variance, or coefficient of variation under the specified conditions of measurement.
- The 'specified conditions' can be, for example, repeatability conditions of measurement, intermediate precision conditions of measurement, or reproducibility conditions of measurement (see ISO 5725-1:1994).
- Measurement precision is used to define measurement repeatability, intermediate measurement precision, and measurement reproducibility.
- Sometimes "measurement precision" is erroneously used to mean measurement accuracy.

Preventive Action:

Action to eliminate the cause of a potential nonconformity or other undesirable potential situation. (ISO 9000, 3.12.1). Note the term "**preventative action**" is not the favoured term.

Note 1 to entry: There can be more than one cause for a potential nonconformity.
Note 2 to entry: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

Procedure:

Specified way to carry out an activity or a process. (ISO 9000, 3.4.5)

- Procedures may, or may not, be documented.

Proficiency Testing:

Determination of laboratory testing performance by means of inter-laboratory comparisons. (ISO/IEC 17043:2010)

Quality Control Sample:

A sample (i.e., test sample or control sample/standard) used either singly or in replicate, as appropriate, to monitor performance characteristics.

Quality Manual (QM):

Specification for the quality management system of an organization. (ISO 9000, 3.8.8)

Note 1 to entry: Quality manuals can vary in detail and format to suit the size and complexity of an individual organization.

A quality manual can be considered a document stating the quality policy and quality practices of an organization. The key word, which warrants a closer look, is quality policy.

Quality Objective:

Objective related to quality. (ISO 9000, 3.7.2)

Quality Policy:

Policy related to quality. (ISO 9000, 3.5.9)

The quality policy is a statement of a laboratory's overall intentions and direction related to quality as formally expressed by top management. The quality policy will have a number of supporting quality objectives. Generally the quality policy is consistent with the overall policy of the organization and provides a framework for the setting of quality objectives.

Quality Management System:

Part of a management system with regard to quality. (ISO 9000, 3.5.4)

The system to manage and direct the operations of an organisation with regard to quality. Quality systems may be considered to be the organisation, functioning and inter-relation of the resources, policies and procedures necessary to carry out the quality objectives. Key words, which require further explanation, are resources and procedures.

Reagent Blank:

Blank which undergoes processing identical to that carried out for calibration standards. Blank results are used to assess contamination and establish the baseline used in the calibration.

Reference Measurement Standard:

Measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location. (VIM, 5.6)

Reporting Detection Limit:

The lowest concentration that will be reported for a specific method.

Resources:

Resources include facilities, personnel, equipment, and work instructions: (Not defined elsewhere)

- test methods and other supporting work instructions,
- procedures necessary to ensure sample integrity,
- procedures necessary to ensure test organism integrity,
- equipment operation instructions,
- quality control procedures and
- worksheets used in the conduct of laboratory testing

Robustness:

The degree to which a measurement procedure or method is immune to variations induced by operational parameters including, but not restricted to, environmental factors, chemical parameters, electrical/site services and human activity. [Taylor, 1987]

Sample:

For testing laboratories, a sample generally refers to the material being tested (e.g., water, soil, air, etc.) For the purposes of this document, the term sample is synonymous with the term test item in ISO/IEC 17025.

SI (Système International d'Unités):

The name (International System of Units) adopted by the 11th General Conference on Weights and Measures (1960) for the recommended practical system of units of measurement.

The base units are a choice of seven well-defined units which, by convention, are regarded as dimensionally independent: the metre, the kilogram, the second, the ampere, the Kelvin, the mole, and the candela.

Significant Figures:

The number of figures required to express a numerical determination such that only the last figure is uncertain, which is dependent upon a method's precision.

Test(ing):

Determination of one or more characteristics of an object of conformity assessment, according to a procedure (ISO/IEC 17000, 4.2)

NOTES

- "Testing" typically applies to materials, products or processes.
- In analytical science, a test is a unique combination of matrix, analyte and test method (e.g., ions in water by ICP).
- On most other scientific disciplines, a test is restricted to the search for a characteristic of a material, product, or process.

Traceability (or Metrological Traceability):

Property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty. [VIM 2.41]

NOTES

- For this definition, a 'reference' can be a definition of a measurement unit through its practical realization, or a measurement procedure including the measurement unit for a non-ordinal quantity, or a measurement standard.
- Metrological traceability requires an established calibration hierarchy.
- Specification of the reference must include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.
- For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrologically traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.
- Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.
- A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.
- ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (see ILAC P-10:2002).
- The abbreviated term "traceability" is sometimes used to mean 'metrological traceability' as well

as other concepts, such as 'sample traceability' or 'document traceability' or 'instrument traceability' or 'material traceability', where the history ("trace") of an item is meant. Therefore, the full term of "metrological traceability" is preferred if there is any risk of confusion.

Traceability (of Chemical Measurements):

A property of the result of a measurement, either physical or chemical, or the value of a standard whereby it can be related, with a stated uncertainty, to stated references, usually national or international standards, through an unbroken chain of comparisons.

Trueness (or Measurement Trueness):

Closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value [VIM 2.14].

NOTES

- Measurement trueness is not a quantity and thus cannot be expressed numerically, but measures for closeness of agreement are given in ISO 5725.
- Measurement trueness is inversely related to systematic measurement error, but is not related to random measurement error.
- Measurement accuracy should not be used for 'measurement trueness' and vice versa.

Uncertainty of Measurement (or Measurement Uncertainty):

Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used. [VIM 2.26]

NOTES

- Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.
- The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.
- Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.
- In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quantity value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

Also note that there is no such thing as "**Measurement of Uncertainty**." Uncertainties are not measured: they are estimated.

Verification:

Provision of objective evidence that a given item fulfils specified requirements. [VIM 2.44]

EXAMPLE 1 Confirmation that a given reference material as claimed is homogeneous for the quantity value and measurement procedure concerned, down to a measurement portion having a mass of 10 mg.

EXAMPLE 2 Confirmation that performance properties or legal requirements of a measuring system are achieved.

EXAMPLE 3 Confirmation that a target measurement uncertainty can be met.

Note 1 to entry: When applicable, measurement uncertainty should be taken into consideration.

Note 2 to entry: The item may be, for example, a process, measurement procedure, material, compound, or measuring system..

Note 3 to entry: The specified requirements may be, for example, that a manufacturer's specifications are met.

Note 4 to entry: Verification in legal metrology, as defined in VIML, and in conformity assessment in general, pertains to the examination and marking and/or issuing of a verification certificate for a measuring system.

Note 5 to entry: Verification should not be confused with calibration. Not every verification is a validation (3.9).

Note 6 to entry: In chemistry, verification of the identity of the entity involved, or of activity, requires a description of the structure or properties of that entity or activity.

1.4.3 Documents that Accreditation Bodies use to set Requirements

All accreditation bodies will provide specific criteria on certain aspects of demonstrated competence. They will include accreditation policies regarding the following, amongst others:

- Traceability
- Uncertainty
- Method Validation
- Detection Limits
- Acceptable range of measurement
- Internal Audit / Management Review
- Use of IT

1.5 Where to Start?

1.5.1 A Quality System based on Principles

With the publication of ISO 9000:2000, based on a set of management principles, there was a perceived inferiority of ISO/IEC 17025, because it claimed association with the now-obsolete version of ISO 9000 and it appeared to lack a basis in broad-based principles.

During the ISO/CASCO work of aligning ISO/IEC 17025 with the management system requirements of ISO 9000:2000, a set of principles mostly based on science were developed to demonstrate that ISO/IEC 17025 was more than a simple, sector-specific application of ISO 9000. ISO/IEC 17025 is based on different principles than those used for ISO 9000, although these had not been formally articulated within the work of the original ISO/CASCO committee that drafted ISO/IEC 17025.

There followed quick acceptance of the revision of ISO/IEC 17025 from ISO/TC 176, the committee that had developed both the management system principles behind ISO 9000 and the resulting ISO 9001 standard.

The set of principles that helped carry this argument are contained in the MOTIVA 17025 Guide. They are:

- Capacity
- Exercise of Responsibility
- Scientific Method
- Objectivity of Results
- Impartiality of Conduct
- Traceability of Measurement
- Repeatability of Test
- Transparency of Process

Capacity

Concept that a laboratory has the resources (PEOPLE with the required skills and knowledge, the ENVIRONMENT with the required facilities and equipment, the QUALITY CONTROL, and the PROCEDURES) in order to undertake the work and produce COMPETENT results.

Exercise of Responsibility

Concept that persons in the organization have the authority to execute specific functions within the overall scope of work – and that the organization can demonstrate accountability for the results of the work.

Scientific Method

Concept that the work carried out by the organization is based on accepted scientific approaches, preferably consensus-based, and that any deviations from accepted scientific approaches can be substantiated in a manner considered generally acceptable by experts in that field.

Objectivity of Results

- Concept that the results produced within the scope of work of the organization, are mainly based on measurable or derived quantities.
- Concept that subjective test results are produced only by persons deemed qualified to do so and that such results are noted as being subjective, or are known by experts in that field of testing to be mainly subjective.

Impartiality of Conduct

Concept that the pursuit of competent results through the use of generally accepted scientific approaches is the primary and overriding influence on the work of persons executing tests - all other influences being considered secondary and not permitted to take precedence.

Traceability of Measurement

- Concept that the results produced, within the scope of work of the laboratory, are based on a recognised system of measurement that derives from accepted, known quantities (SI system) or other intrinsic or well-characterised devices or quantities.
- Concept that the chain of comparison of measurement between these accepted, known quantities or intrinsic devices or quantities, and the device providing the objective result, is unbroken for the transfer of measurement characteristics, including uncertainty, for the whole of the measurement chain.

Repeatability of Test

Concept that the test which produced the objective results, will produce the same results, within accepted deviations during subsequent testing, and within the constraints of using the same procedures, equipment and persons used during a previous execution of the test.

Transparency of Process

Concept that the processes existent within the laboratory producing the objective results, are open to internal and external scrutiny, so that factors which may adversely affect the laboratory's pursuit of objective results based on scientific method, can be readily identified and mitigated.

These eight principles may not cover every aspect of every requirement in the standard, but they are broad enough to allow persons working in laboratories to appreciate the reasons behind most of the individual requirements. They may also allow assessors to use their professional judgement in assessing the conformance of a laboratory to each of the requirements within the standard.

1.5.2 The Laboratory Quality Policy and Quality Objectives

The Quality Policy is the most prominent statement that can be made in laboratory concerning the implementation of its own quality system. It may be subordinate to its own “mission statement” or its “value statement” but it is the statement that sets the stage for how it will deal with the issues of overall competence and quality.

The Quality Policy may be a single statement, or it may be a series of subordinate objectives (quality objectives) that support the overall approach and define the effort (what to do) the laboratory will expend in establishing and maintaining its demonstrated competence.

These objectives can be stated, more or less, as follows. These objectives can also be used as the basis for structure of the quality system. Note that this is only one possible approach to developing the structure of a quality system. There are many other possible methods of doing this.

1.5.2.1 Documented System (Chapter 1)

Implement and maintain a quality system that is documented and incorporates adequate review, audit and internal quality control. Use the system to deliver continual improvement and support impartiality and transparency.

This objective encompasses all of the effort associated with document control, internal audit and management review. It includes all quality system procedures that may not be directly related to testing, such as purchasing. It also includes the formal set of obligations that the laboratory voluntarily undertakes to allocate responsibilities (including authority and accountability) to persons for all aspects of operations within the laboratory. All responsibilities, from management to the most basic support functions are normally covered.

1.5.2.2 Trained and Qualified Personnel (Chapter 2)

Adequately train, supervise and demonstrate continuing proficiency of the persons within the laboratory to carry out assigned activities. Establish goals for this objective and track their attainment.

This objective encompasses all of the effort associated with selecting, training, and qualifying personnel and monitoring their continuing proficiency.

1.5.2.3 Valid Methods (Chapter 3)

Select and validate appropriate test methods (and related work instructions) and incorporate adequate quality control of the methods.

This objective encompasses all of the effort associated with the development and maintenance of all testing methods used in the production of valid results, and all of the procedures in support of this effort.

1.5.2.4 Supporting Infrastructure (Chapter 4)

Acquire and make use of facilities, equipment, supplies and services that are appropriate to the work. Ensure they are functioning properly and meet or exceed required specifications.

This objective encompasses all of the effort used to acquire, use, calibrate and maintain laboratory measuring equipment, and ensure the adequacy of accommodation.

1.5.2.5 Traceability of Measurement (Chapter 5)

Produce only traceable results, supported by a system of measurement traceable to the International System of Units (SI), through a National Metrology Institute (NMI), and accorded uncertainties appropriate to requirements.

This objective encompasses all of the effort used to propagate uncertainties to measurements and measurement equipment, including chemical standards, and estimate uncertainties associated with test and calibration results.

1.5.2.6 Integrity of Samples and Sample Handling (Chapter 6)

Handle all samples, from reception to disposal, with adequate security, protection of integrity, and defined processes for their receipt, identification, checking, routing, storage and disposal.

This objective encompasses all of the effort used to ensure chain of custody of samples, determination of fitness for purpose of all samples, retention of sample integrity, and transparent association of samples with test report results.

1.5.2.7 Quality Assurance (Chapter 7)

Develop and maintain adequate data management procedures that incorporate appropriate security, recording, calculation, validation, authorisation, transmittal, storage and disposal of all test data and related records.

This objective encompasses all of the effort used to provide for adequate quality assurance of test and calibration results.

1.5.2.8 Laboratory Workload (Chapter 8)

Manage the workload of the laboratory so as to maintain the ability to produce valid and competent results.

This objective encompasses all of the effort used to plan, allocate and verify resources and resource availability before the acceptance of work. This includes management direction and allocation of resources that incorporates appropriate turnaround time and verification of resource availability

1.5.3 The Resulting Quality System Structure and the Advantages of this Approach

The approach given in the eight quality objectives above, have the advantage of focussing the laboratory's quality effort on a set of attainable objectives. Each of the eight objectives above can provide the laboratory with the following.

- Articulation of one specific system objective for each part of the laboratory quality system.
- Assurance that each objective is already in line with the requirements of ISO/IEC 17025
- Identification and allocation of the resources (time, money, personnel, effort etc.) to accomplish each objective
- Identification of the processes/procedures that can be implemented within the laboratory to attain each objective
- Melding of these disparate parts of a quality system into one complete and congruent whole
- An appropriate set of requirements (laboratory quality system) against which internal audits and can be conducted and which management can review for suitability.

This is the most basic quality system structure that meets the requirements of ISO/IEC 17025. The various parts of this most basic structure will be dealt with in the chapters that follow. They will not be dealt with in this order, as "flow" and "importance" are not the same considerations in the design and implementation of a quality system.

Chapter 2 – Basic Technical Requirements

2.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** the main technical requirements of ISO/IEC 17025;
- **identify** appropriate methods for demonstrating continuing competence of personnel.
- **identify** the accommodation and equipment resources required to support the quality system;
- **understand** the considerations for sampling and sample handling;
- **understand** the most appropriate means for implementing quality control and quality assurance;
- **identify** the requirements for reporting results, and

2.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 2.1

How can a laboratory document and/or demonstrate the continuing competence of its staff? (Select all that apply.)

a. The competence of laboratory staff can only be demonstrated to an accreditation body.
b. The laboratory retains records of demonstrated competence on file.
c. Internal auditors determine the competence of laboratory staff.
d. Competence is only determined to a staff member qualified to make such determination.

Discussion Activity 2.2

When is a laboratory required to undertake method validation? (Select all that apply.)

a. When a significant number of staff that conduct the procedure are changed.
b. When the reference procedure or method is modified.
c. When the laboratory changes premises.
d. When significant equipment associated with the procedure is changed.
e. All of the above.

Discussion Activity 2.3

How does a laboratory document that it is exercising appropriate control of its environment and its equipment? (Select all that apply.)

a. Environmental conditions are monitored.
b. Environmental conditions are recorded.
c. Changes to environmental conditions are noted for some action, as appropriate.
d. Non-conforming environmental conditions are treated as with any other NC.
e. All of the above.

Discussion Activity 2.4

How can a laboratory implement sampling requirements for samples taken by an outside agency? (Select all that apply.)

a. A laboratory cannot force samples to be gathered as per its own needs.
b. A laboratory can provide written sampling instructions to all who gather samples for it to test.
c. A laboratory can require the provision of evidence of sampling in accordance with its procedures.
d. None of the above.

Discussion Activity 2.5

What are the best methods for implementing quality control / quality assurance in a laboratory? (Select all that apply.)

a. Hire more QA staff.
b. Allow another staff member to see the results.
c. Implement statistical process control (control charting) for all results.
d. Have the client conduct the QA on the results.
e. Let the accreditation body conduct QA on all results.

2.3 Basic Requirements (Clause 7)

Clause 7 of ISO/IEC 17025 contains the most important elements of the standard – the technical requirements. All of Clauses 4, 5, 6 and 8 are devoted to supporting the laboratory's ability to implement the requirements of Clause 7.

The laboratory quality system is there to support the laboratory's production of technically valid results and implement the technical requirements. Not the other way round.

The first principle behind the standard (Capacity) contains a list of things that must exist in a laboratory for it to demonstrate competence. These are:

- People with the skills and knowledge,
- An environment with the facilities and equipment,
- Quality control, and
- Procedures

Like all technically-oriented record keeping, all of the things in these lists can only be demonstrated through records. In the technical community, we tend to live by the premise that if "it" was not written down, "it" cannot be proven. It is not possible for us to prove that "it" actually happened. In other words, unless "it" was documented and recorded, "it" did not happen.

Science, the study of phenomena, trains us to "write it all down" and it is inherent in the requirements of ISO/IEC 17025. This is the single biggest reason why ISO/IEC 17025 is so prescriptive, compared to ISO 9001. Everything must be documented, including traceable records.

2.4 People with the Skills and Knowledge (Clause 6)

We may all be used to documenting our procedures, recording observations and results, documenting that tests and measurements have been validated, documenting equipment maintenance, and documenting other aspects of laboratory operations, but we often fail to document the competence of the laboratory staff.

Some guidelines can be used to document the competence of staff. The first is that only those documents and records that support the laboratory's demonstration of competence are relevant. Some personnel records should not be seen by auditors and assessors, such as pay and health records. These should remain confidential between the person and the laboratory or its parent organization. Others are very important in the laboratory's demonstration of competence. The challenge is to determine which is which.

ISO/IEC 17025 lists some of the requirements for documenting personnel competence. In essence, how does the laboratory record that people selected for the following functions met selection criteria?

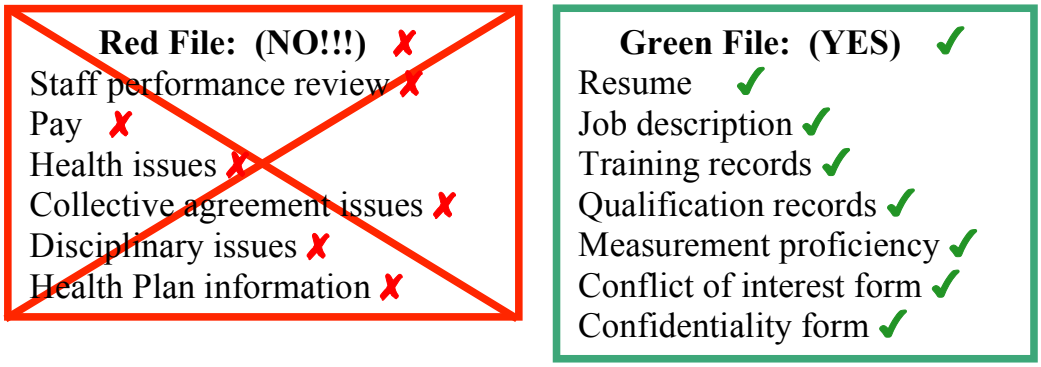
- Perform sampling
- Conduct tests
- Issue reports
- Give opinions and interpretations
- Operate specific types of equipment
- Conduct quality control / quality assurance
- Conduct internal audits

- Authorise procedures

The second guideline that can be used is that the laboratory and its parent organization can segregate the personnel information legitimately available to auditors and assessors from personnel information that should not be seen by them. This can be done in the same file, with one piece of a personnel file that can be extracted and presented for examination, while the other remains in safekeeping.

Consider, for example, a personnel file kept in a central file system of a large organization. It has a red cover, implying that it cannot be viewed or removed from the central file storage without appropriate permission. Within this red file is a smaller green file. It contains personnel information on the documented competence of the person to support the overall demonstration of competence of the laboratory.

Pictorially, this is what the split looks like:



The red file is **NOT** for review by an auditor or assessor, including internal auditors. It contains no information that is relevant to the work of either an auditor or an assessor.

Conversely, the information in the green file responds to the questions posed an auditor or an assessor. An assessor is required to review the contents of the green file.

2.5 Environment with the Facilities and Equipment (Clause 6)

Control of the environment and the equipment in the laboratory are directly related to a laboratory's ability to produce technically valid results. Very few scientific tests can be undertaken in a testing laboratory without some sort of environmental control and control of equipment.

Clause 6 of ISO/IEC 17025 provides detailed information on what steps should be taken to control these two different types of "testing tools."

2.6 Quality Control (Clause 7.7)

This clause aims to have the laboratory identify methods to exercise quality control over their testing and calibration processes and quality assurance on the results.

The most common tool for quality control used by some laboratories in some accreditation programs is a proficiency test conducted for accredited parameters. Four concentrations twice yearly for all parameters is a good method of measuring the quality of laboratory testing processes. Few accreditation programs require this level of stringence.

PT is not, however, the only tool available to a laboratory. The standard gives five options and backs them up with a second sub clause (7.7.1) that requires the QC methodologies used to be monitored and analysed. The five options are:

- use of reference materials or quality control materials;
- use of alternative instrumentation that has been calibrated to provide traceable results;

- functional check(s) of measuring and testing equipment;
- use of check or working standards with control charts, where applicable;
- intermediate checks on measuring equipment;
- replicate tests or calibrations using the same or different methods;
- retesting or recalibration of retained items;
- correlation of results for different characteristics of an item;
- review of reported results;
- intralaboratory comparisons;
- testing of blind sample(s)

The most common tool for quality assurance is the "second set of eyes" cast upon the results derived, produced, transcribed and reported. Any one of these processes can induce error into the final product and laboratories may use a number of methods to mitigate adverse results.

2.7 … and Procedures…. (Clause 7.2)

Method selection and method validation are some of the most time consuming activities in an analytical laboratory. For most mechanical, electronic, and other types of laboratories, the testing processes are normally included within the text of the test standard and commonly used equipments are deemed sufficient to have the laboratory consider the method validated (if it only follows the written procedure).

Analytical laboratories are not so lucky and they must validate all methods used to determine their fitness for purpose within their own laboratory.

Method validation for analytical laboratories is extremely well covered in the Eurachem Guide, *The Fitness for Purpose of Analytical Methods*.

For most accredited laboratories, the requirements of Clause 5.4 are amplified by interpretive requirements given in accreditation body documentation.

2.8 Sampling and Sample Handling (Clauses 7.3 and 7.4)

For many types of tests, sampling provides the greatest sources of uncertainty. For others, it can be negligible. Regardless of its effect, the standard seeks to have laboratories develop and implement procedures to ensure that whoever does the sampling, the resulting sample is assessed for fitness prior to the test.

This may require the laboratory to create very explicit sampling requirements and procedures whenever sampling is being done by an outside agency. Basically, the outside agency is not going to decide if the sample is fit for testing. Only the lab can decide this and the decision has to be based on known and documented procedures and records. Records need to include demonstration that the written sampling procedure was followed, regardless of who did the sampling.

Once a sample is received by the lab, the standard seeks to have the laboratory treat it so as to achieve the following:

- Maintain the sample's integrity and fitness for testing.
- Maintain the chain of custody of the sample so as to demonstrate that its integrity and fitness for testing was not compromised throughout the process.
- Identify all persons who may have had cause to handle, treat, or test the sample.
- Identify all locations or stations handling, storing or involved in testing the sample, and
- Associating the sample with other pertinent laboratory / test information such as the client details and the report details.

2.9 Reporting the Results (Clause 7.8)

This clause in the standard is very simple in that it provides requirements to testing labs (7.8.2 and 7.8.3) and calibration labs (7.8.2 and 7.8.4). The differences between 7.8.3 and 7.8.4 are the differences between publishing testing and calibration results.

7.8.3.1 c. is very explicit in the requirements for when a testing lab MUST include uncertainties with its results.

7.8.5 is used for those organisations that report only the results of sampling, and 7.8.6 is for the reporting of statements of compliance. In this case, the laboratory must include the impact of uncertainty on such a statement. This is called the Decision Rule.

7.8.7 gives the conditions around which a laboratory may include interpretations and opinions. Normally, these are reserved for a separate part of the report.

The remainder of Clause 5.10 has no surprises until 5.10.9 where the potential for collusion is eliminated by requiring laboratories to always refer to any reports replaced by newer versions when retests are conducted. In other words, the first results, while not presented, are noted in the second report.

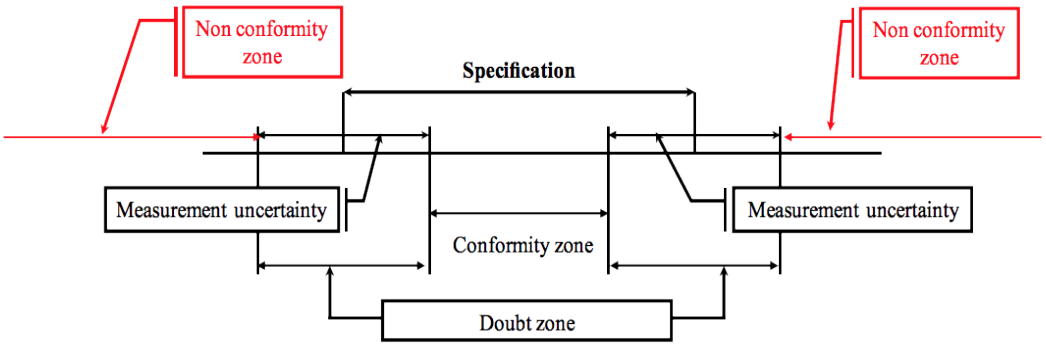
2.10 The Decision Rule (Clause 7.8.6)

ISO/IEC 17025, Clause 7.1.3 states:

> *When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance) the specification or standard, and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.*

2.10.1 Impact of Uncertainty on Statement of Compliance:

Consider the diagram below:



This diagram shows various components to consider in the Decision Rule when making a statement of conformance.

1. The result is in the “Conformity Zone”: Any results here with this amount of uncertainty = PASS
2. The result is in the “Non-conformity Zone”: Any results here with this amount of uncertainty = FAIL
3. The result is in the “Measurement Uncertainty Zone”: Any results here with this amount of uncertainty = We don’t know??

Consider the diagram on the right:

This diagram shows various components to consider in the Decision Rule when making a statement of conformance.

1. The result is Case 1, clearly below the Upper limit: Any results here with this amount of uncertainty = PASS
2. The result is Case 4, clearly beyond the Upper limit: Any results here with this amount of uncertainty = Fail
3. The result is Case 2 or Case 3, partly below and partly beyond the Upper limit: Any results here with this amount of uncertainty = We don't know??

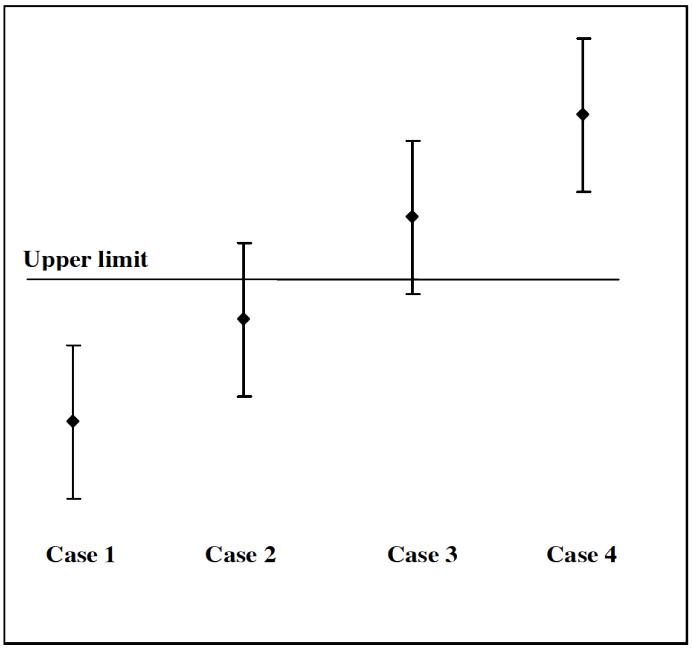


Fig.1 Compliance with specification for an upper limit. Compliance statements may be expanded to explicitly state whether compliance concerns an upper or a lower limit of specification using a coverage probability of 95 %.

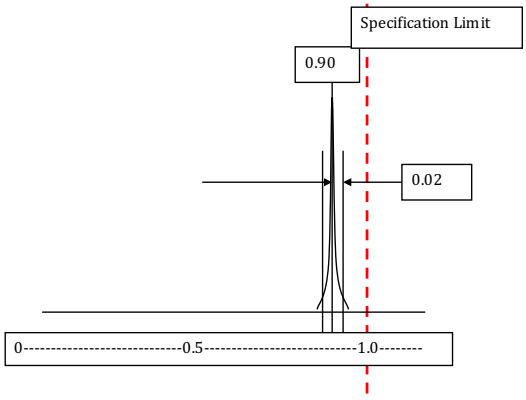
2.10.2 Examples of Decision Rule

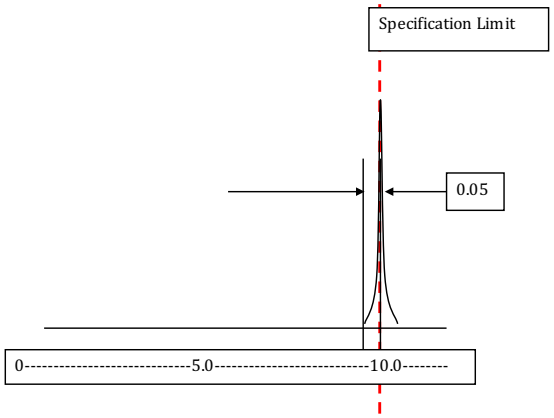
Example 1. Measuring Mercury (Hg) in Drinking Water (≤ 1.0 mg/L):

Uncertainty of measurement = ± 0.02 mg/L

Decision Rule

- If result, incorporating uncertainty, is .98 mg/l or less, the sample is **OK = PASS**.
- If result, incorporating uncertainty, is .99 mg/l or greater, the sample is **NOT OK = FAIL**





Example 2. Length of a 10 cm Steel Ruler (10 cm ± 0.05 cm):

Uncertainty of measurement = ± 0.05 cm

Decision Rule

- If total length of ruler, incorporating uncertainty, is between 9.98 cm and 10.02 cm, the sample is **OK = PASS**.
- If total length of ruler, incorporating uncertainties is outside of these limits, the ruler **DOES NOT PASS**

Chapter 3 – Measurement Requirements

3.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **understand** the broad concept of measurement traceability,
- **identify** the laboratory accreditation requirements for traceability.
- **Identify** the impact of uncertainty on calibration and vice versa

3.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 3.1

Identify the requirement for laboratories to ensure traceability of measurement. What are the documents that govern? (Select all that apply.)

a. Clause 5.10 of ISO/IEC 17025.
b. GUM Section 3.2
c. VIM Clause 2.41.
d. Clause 5.6 of ISO/IEC 17025
e. All of the above.

Discussion Activity 3.2

How may laboratories ensure that uncertainties have been competently propagated to their working instruments? (Select all that apply.)

a. The laboratory calibrates its own working instruments from its externally calibrated reference instruments.
b. The NMI calibrates all instruments.
c. An accredited calibration laboratory calibrates the working instruments.
d. The customer calibrates the working instruments.
e. All of the above.

Discussion Activity 3.3

What do you believe is the best measure of quality in a laboratory? (Select all that apply.)

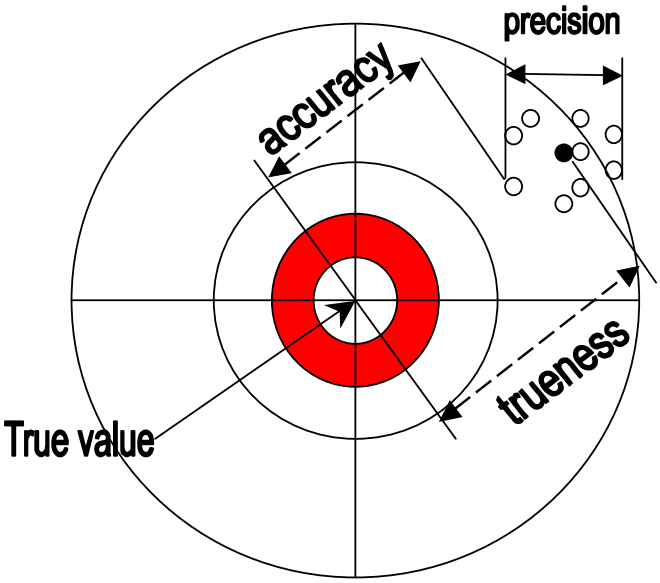
a. Findings on assessment reports.
b. The customer cost of services.
c. Turn around time.
d. The uncertainty of test and calibration results.
e. All of the above.

3.3 Basic Concepts of Measurement

3.3.1 Basic Definitions Involving Uncertainty of Measurement

The most comprehensive definitions related to measurement traceability and measurement uncertainty is given in the International Vocabulary for Metrology (*Vocabulaire internationale de metrologie – VIM).* Review the definitions related to uncertainty, traceability and calibration in Section 1.4.2 above.

Consider the following diagram.



This diagram shows a series of results as the small white dots. They are not the same as the actual value one would get if we lived in a perfect world. This "perfect" or "true" value is represented by the centre of the target.

The black dot represents the average of all the results generated. IT IS NOT A RESULT ITSELF. It is also called the "mean" or "average" or "mean point of impact" (MPI) of the set of generated results. If a laboratory has produced a set of results from one large sample, then they may report this average as representative of the whole set.

How "accurate" are these results? It depends. Let's examine the concept of "accuracy."

"Accuracy", is a *qualitative* term only. It refers only to the concept of *closeness* to a true value. If one considers only the numbers, then one might examine the *quantitative* equivalent considerations. These are "trueness" and "precision".

Trueness is also a *qualitative* term representing where the white dots are with relation to the true value. Or the true value to the black dot (mean).

Precision is defined as the closeness of agreement between independent test results obtained under prescribed stipulated conditions. (ISO 3534-1, 3.14 amplified by ISO 5725-1 to 6).

NOTES –

- Precision depends only on the distribution of random errors and does not relate to the true value or the specified value.
- The measure of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results. Less precision is reflected by a larger standard deviation.
- "Independent test results" means results obtained in a manner not influenced by any previous result on the same or similar test object. Quantitative measures of precision depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme conditions.

Precision is how dispersed the group of white dots are from each other and from the black dot = "dispersion". How wide is the spread in values represented by the white dots?

Therefore, no one measurement can be given a value of accuracy. It can only be given a quantifiable value of precision.

It is important to understand that trueness and precision are independent of each other. One has **nothing** to do with the other.

If it were possible to measure *trueness*, the distance of the black dot to the centre of the target would be a representation of how close the set of results came to the true value. The direction of the black dot from the true value can also be thought of as "bias".

This is only one question that can be answered by an estimation of the uncertainty of measurement associated with the test result:

> *What is the likelihood that any given test result will fall within this region (area) surrounding the reported result (black dot)?*

The answer is quantifiable and objective. It gives us a number. What is missing from our consideration of these test results is an equivalent confidence in the distance of the mean from the true value. How has trueness affected our result? We will discuss this in the next section.

3.3.2 Other Concepts related to Traceability and Uncertainty

Uncertainty can be considered as the result of calibrations.

Testing laboratories produce test results. The test result is the product of a process of sampling and measuring.

Calibration laboratories conduct comparisons of the performance of artefacts of unknown performance parameters against those of known performance. The performance of both the known and the uncharacterised artefacts are given in the uncertainties that these devices are capable of producing under a given set of conditions. The characterisation of the artefact whose performance parameters are not known (the instrument being calibrated) will result in a statement of its uncertainty that says it is capable of producing measurement results within specified uncertainties for each range of measurement included in that calibration process. The result of calibration is, therefore, the set of uncertainties associated with the artefact calibrated.

Uncertainty is the best indication of the quality of a test result.

From the previous diagram, uncertainty relates primarily to the consideration of "precision". If the spread of results is very small, that is an indication that the laboratory has very good control of its processes. It can produce test results with relatively small uncertainties.

Uncertainty can be a warning signal to a regulatory agency.

When a laboratory produces a result that is close to a specification limit, the uncertainty associated with that result can provide an indication of the potential for exceedence.

3.4 Uncertainty of Measurement

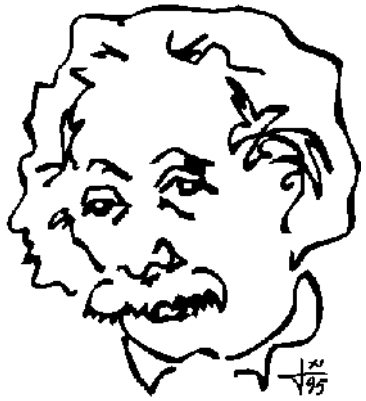
3.4.1 What are the international authoritative documents on Uncertainty?

The premier publication on this subject is: "Evaluation of Measurement Data - Guide to the Expression of Uncertainty in Measurement" (GUM) published by BIPM, IEC, IFCC, ILAC, ISO, IUPAC, IUPAP, and OIML as JCGM 100: 2008.

These eight organizations collaborated to publish it as a free download at:
http://www.bipm.org/utils/common/documents/jcgm/JCGM_100_2008_E.pdf.

3.4.2 A Measure of Measurement Quality

If perfection in a testing laboratory were to be described, and perfection was based on the principles behind ISO/IEC 17025, the description would probably look like this:



"We can produce consistent results, day after day, within the ninety-five percent confidence region at specified uncertainties."

Drawing by Iutta Waloschek.
From the website of the University of St. Andrews, Scotland.
http://www-gap.dcs.st-and.ac.uk/~history/PictDisplay/Einstein.html

This attitude, the inherent dedication to the science and the apparent lack of flash and colour in the person making the statement are the very characteristics that engender trust in the work of a laboratory. In other words, this is a PERFECT lab – and 5% of their results may still be outliers.

Remember that ISO/IEC 17025 is only concerned with competence, not the provision of business solutions. It seeks to provide laboratories with a system to help it achieve this state of "perfection" characterised by consistency and competence.

Other than those clients that may now need uncertainties because a regulator requires them to have it, most clients will not understand the need for uncertainties. Those that do understand will use the information as a measure of quality of laboratory results.

Overall, lab clients will wish to receive uncertainties for three reasons.

- Whenever regulators want them to have it or produce it.
- To be warned about a specification limit being approached
- To help interpret results and their validity/application

3.4.2.1 An Example

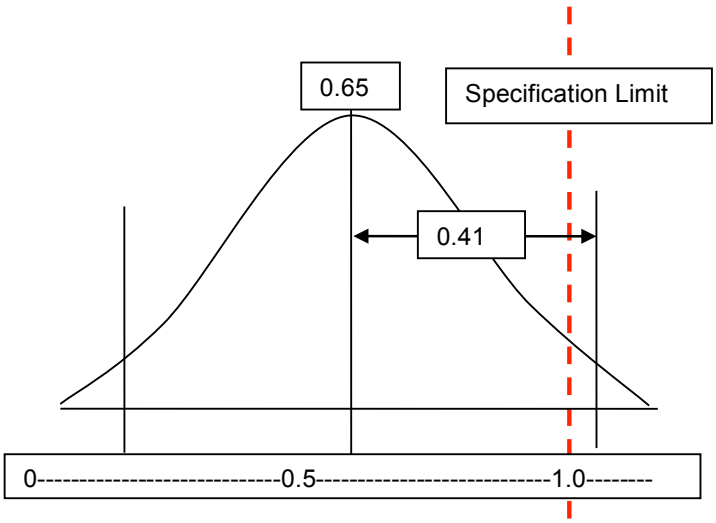
Given a regulatory specification limit of 1.0 mg/L of lead in wastewater, one might think that a result of:

0.65 +/- 0.41 mg/L (Case 1) is better than

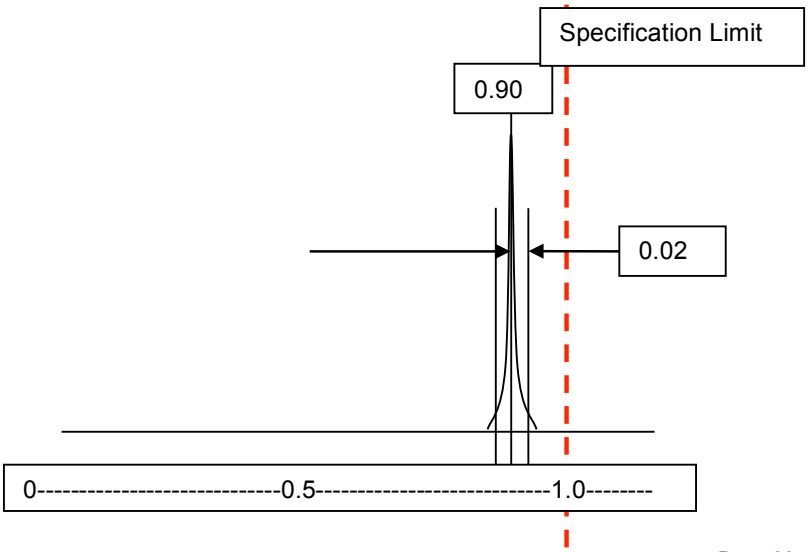
0.90 +/- 0.02 mg/L, (Case 2) but the regulators would disagree.

Here is why:

Case 1



Case 2



3.4.2.2 The Rationale

Which of these two labs has better control of its testing processes? The regulator sees the Case 1 as a warning of possible problems, and Case 2 as tight, but acceptable.

The first regulatory body in North America to appreciate the effect of uncertainty to submitted results was the Greater Vancouver Regional District (GVRD). Their policy on "Measurement Variability in Wastewater Samples" was created in 2002 and was a model policy.

Retesting is required only when the measurement plus the uncertainty indicates possible exceedence. Enforcement action is deemed appropriate only when the measurement itself exceeds the specification limit.

Finally, regulators may be called upon to compare conflicting results. In this instance, the results demonstrating better control of process (uncertainty) and the better control of metrological traceability (trueness) would be considered more reliable. **Uncertainty is an indication of the quality of a result.**

3.4.2.3 The Laboratory Duty of Care and Duty to Warn

In law, implicit in the work done by persons who have specific expertise pertaining to legislation or a regulation, are requirements for duty of care and duty to warn. For example, a licensed civil engineer is required under law, as are most professions, to provide a **duty of care** for the work they conduct. This duty is owed primarily to the person contracting their services, but may also include the public. It includes ensuring that all reasonable steps have been taken to ensure the safe completion of the work and that no threat is posed to the health, welfare and safety of the public.

Whenever there may be deviation from this happy set of circumstances, there is a duty to warn. Whenever there is perceived threat to the health, welfare, and safety of persons, there is a duty to warn. Whenever the work is completed but may not be safe, there is a duty to warn. Whenever information indicates that an infraction to a regulation has been committed, there is a duty to warn. Whenever some knowledge or data appears that may indicate non-compliance with a regulation… then professionals are normally required to exercise the **duty to warn**. This duty involves providing information to someone responsible for the matter, or to the person or persons who caused the professional to undertake the work in the first place.

Regulatory authorities also exercise these duties in the environmental field. Almost all persons employed by a regulatory authority to oversee enforcement will exercise these duties. Some provinces have strict laws regarding the duty of care and duty to warn. Many licensing bodies across Canada publish disciplinary proceedings every month concerning professionals who have not done. In Ontario, the Safe Drinking Water Act requires laboratory staff to be held personally responsible for not doing so.

In accordance with ISO/IEC 17025, laboratories are required to provide their estimates of uncertainty under the following conditions:

- When so instructed by a client
- When it is relevant to the validity or application of the test result,
- When the uncertainty affects compliance to a specification limit

The client is in control for the first one, but the validity or application of the test result is entirely within the knowledge capabilities of the laboratory. This is because ISO/IEC 17025 requires the laboratory to acquire, document and retain this information prior to doing the work. Laboratory professionals understand the science and know whether test results are suitable for a specific application.

3.4.2.4 Uncertainty as a legal consideration (again).

Consider a fictitious courtroom in Somewhereland. An environmental regulator is pursuing a company for dumping bad stuff on good soil. The lawyer for the prosecution is completing his examination of his final witness, a lab manager whose test results were used by the regulatory agency to bring the company to court. The lab manager is just finishing up his their testimony,

"…..and these results were produced with an uncertainty of plus/minus 4 milligrams per litre of soil."

"Uncertainty…?"

"Yessir, uncertainty."

"Do you mean to say, Dr. Jones, that you are not certain about your results?"

"No sir, I do not mean to say that. The scientific term "uncertainty" refers to the confidence I can mathematically assign to those results which lie within 2 standard deviations of the stated value."

"So…when you say 'uncertainty,' you really mean 'confidence'."

"Yes sir, that is correct."

"Thank you Dr. Jones. Your Honour, the prosecution rests its case."

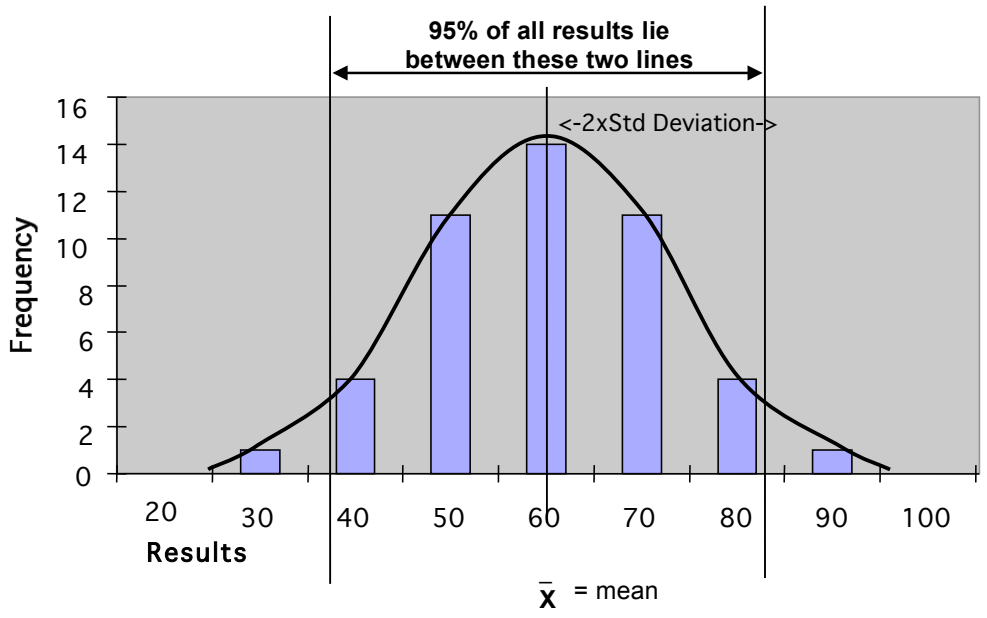
3.4.3 What does Uncertainty look like?

Here are 46 results taken from one sample of a material to establish a value of something measured.

For the purposes of this example, we will use concentration of some analyte in water as the parameter under consideration.

Test #	Value	Test #	Value	Test #	Value	Test #	Value	Test #	Value	Test #	Value
1	61	9	69	17	53	25	61	33	53	41	61
2	69	10	78	18	61	26	53	34	61	42	78
3	61	11	61	19	69	27	69	35	91	43	69
4	69	12	39	20	31	28	61	36	69	44	61
5	39	13	53	21	53	29	69	37	53	45	53
6	69	14	78	22	69	30	53	38	61	46	61
7	61	15	61	23	61	31	53	39	39		
8	53	16	39	24	53	32	69	40	78		

The average of these results is 60.6. The laboratory might chose to report this average as their reported result. When these results are analysed statistically, they produce a distribution curve that looks like this:



Without going into the calculations, the uncertainty of this result can be **estimated,** based on this distribution of data, to be:

+/- 24

The report to the client might then include the following statement:

Reported value is 60.6 +/- 24. This result assumes a coverage factor (k = 2) for the 95% confidence region.

Or

We can be reasonably assured that 95% of all results of this sample lie within the range of 36.6 to 84.6.

3.4.4 Type "A" and Type "B" Estimations of Uncertainty

Type A estimations are based on repeated independent measurements as per the example above.

Type B – estimations are based on the physical set-up of the test and other empirical data. Each contributor is well characterized and its uncertainty is estimated before including it into an overall uncertainty algorithm. An example is in the following expression. In this expression, the uncertainty of a prepared cadmium standard is estimated based on the discrete contributions of three components of the actual measurement, purity (P), mass (m), and volume (V).

$$u_c(c_{Cd}) = c_{Cd}\sqrt{\left(\frac{u(P)}{P}\right)^2 + \left(\frac{u(m)}{m}\right)^2 + \left(\frac{u(V)}{V}\right)^2}$$

This example will be examined in detail later.

3.4.5 Back to the Beginning

If you recall the question given earlier:

What is the likelihood that any given test result will fall within this region (area) surrounding the reported result (black dot)?

You now have an answer.

We can be reasonably confident that 95% of all results of this sample will fall between 36.6 and 84.6.

3.4.6 What about qualitative results – results that have no numbers?

If a result is based on a qualitative evaluation, such as the pass or fail of a paint to look good after a specific environmental conditioning of hot-cold, wet-dry cycles, then no uncertainty can be associated with it. The reason for this is simple.

No numerical result = no ability to estimate the size (quantitative) of the confidence region about which one can have a specific level (quantitative) of confidence of the result.

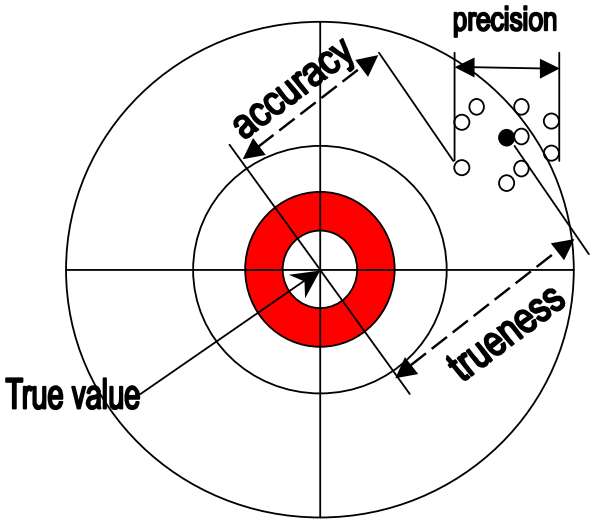
So there is no real way to estimate the accuracy of the measurement. The only controllable factor is trueness, and we need to know how traceability affects trueness.

3.5 Traceability of Measurement

3.5.1 How Traceability affects Trueness

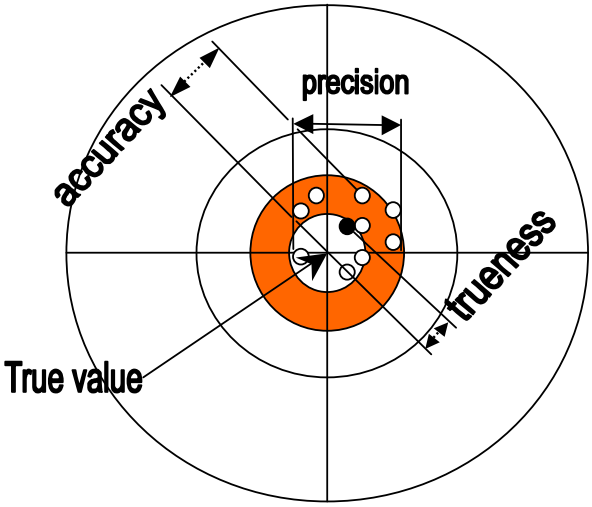
Trueness can be directly affected by ensuring that the uncertainty contributions of all instruments used in a measurement are characterized sufficiently to estimate their contributions to the overall uncertainty of the measurement. In other words, they are properly calibrated and metrologically traceable to the SI.

Recalling the bull's-eye diagram above, it can be said that a lab that controls its processes has better precision. A lab that uses traceable instruments will produce better trueness. The numbers provided by these instruments will be closer to their true value if the uncertainty contributions of these instruments is well characterised.



These two diagrams show how traceability can affect trueness. The first diagram shows results using instruments that have not been well characterised and they do not know, therefore, how these instruments affect the final measurements.

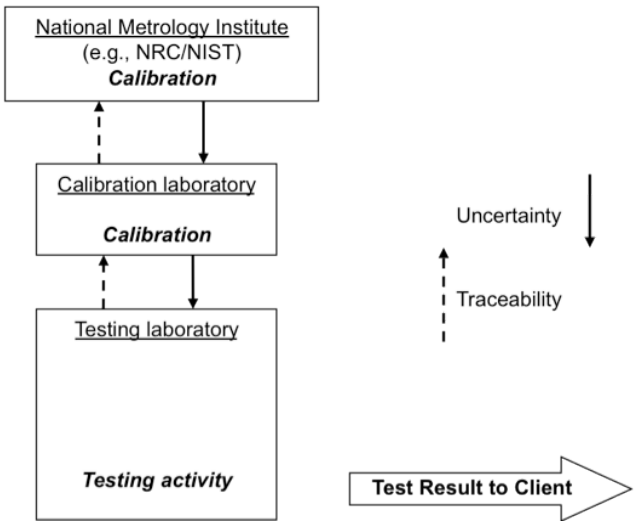
This second diagram shows results using instruments that have been well characterised (calibrated) and the laboratory does know, therefore, how these instruments affect the final measurements.



The precision is the same in both cases. Traceability of measurement (through calibration) has allowed for the production of results that are more reliable.

3.5.2 How Traceability is Achieved

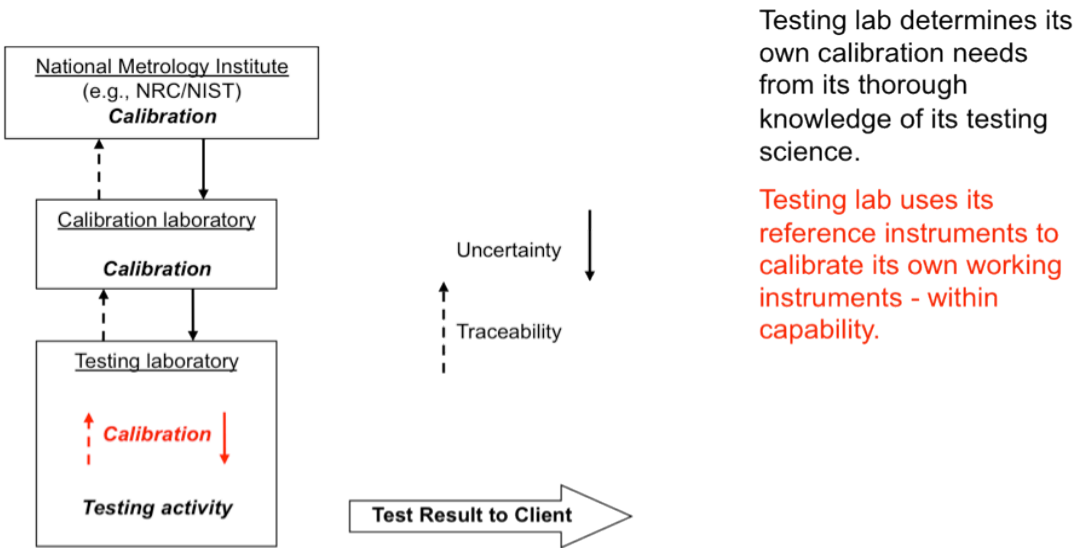
Traceability looks like this….



Testing lab determines its own calibration needs from its thorough knowledge of its testing science.

Testing lab has all of its measurement instruments calibrated by an accredited cal lab

…. OR it looks like this.



Testing laboratories may select either approach depending on the uncertainties that their testing instruments must produce, or what their own calibration work can deliver in terms of uncertainty, or the cost of external calibration versus internal calibration.

Traceability goes back to the SI through a National Metrology Institute (NMI) as Uncertainty is propagated forward to the test result.

At the top of the diagram are all of the NMIs that are responsible in each nation for quantifying specific parameters for use within their nation. Most NMIs have signed a multilateral recognition agreement based on the "demonstration of competence" (e.g., accreditation against ISO/IEC 17025).

The first metrology job of an NMI is to characterise a parameter, such as *mass* or *temperature*, to a specific level of uncertainty. They propagate this uncertainty in support of competent measurements. This affects legal measurements (butcher weigh scales and gas pumps) as well as other fields of science requiring competent measurement.

Each NMI has the ability to conduct measurements with very small uncertainties. They are also able to calibrate the instruments from calibration laboratories seeking to establish traceability to the NMI. This is the start of the traceability chain for a testing laboratory.

"Calibration", "Traceability" and "Uncertainty" are all required at any point in the traceability chain. None of these is deemed present unless ALL are present.

3.5.3 Traceability and uncertainty

Consider our fictitious courtroom in Somewhereland (again). The defence attorney is completing his examination of the lab manager whose test results were used by the regulatory agency to bring the company to court.

> *"Mr. Lab Manager, are your measurements traceable?"*
> *"Yes, they are."*
> *"Can you prove it?"*
> *"…..Hunh???….."*

Traceability involves the competent propagation of uncertainties all along the chain of measurement from

National Standard to the test result produced by a testing laboratory. If uncertainties have not been propagated to the actual test result, the result is not traceable. If it is not traceable, then its "precision" and "uncertainties" may appear OK, but its "trueness" will always be suspect.

3.5.4 Traceability considerations

The components of traceability of measurement (metrological traceability) are contained in Annex A to ISO/IEC 17025.

3.5.4.1 Establishing metrological traceability

Metrological traceability is established by considering, and then ensuring, the following:

a) the specification of the measurand (quantity to be measured);
b) a documented unbroken chain of calibrations going back to stated and appropriate references (appropriate references include national or international standards, and intrinsic standards);
c) measurement uncertainty for each step in the traceability chain measurement uncertainty is evaluated according to agreed methods;
d) each step of the chain is performed in accordance with appropriate methods, and the measurement results and associated, recorded measurement uncertainties;
e) the laboratories performing one or more steps in the chain supply evidence for their technical competence.

The systematic measurement error (sometimes called "bias") of the calibrated equipment is taken into account to disseminate metrological traceability to measurement results in the laboratory. There are several mechanisms available to take into account the systematic measurement errors in the dissemination of measurement metrological traceability.

Measurement standards that have reported information from a competent laboratory that includes only a statement of conformity to a specification (omitting the measurement results and associated uncertainties) are sometimes used to disseminate metrological traceability. This approach, in which the specification limits are imported as the source of uncertainty, is dependent upon:

a) the use of an appropriate decision rule to establish conformity;
b) the specification limits subsequently being treated in a technically appropriate way in the uncertainty budget.

The technical basis for this approach is that the declared conformance to a specification defines a range of measurement values, within which the true value is expected to lie, at a specified level of confidence, which considers both any bias from the true value, as well as the measurement uncertainty.

EXAMPLE: The use of OIML R 111 class weights to calibrate a balance.

3.5.4.2 Demonstrating metrological traceability

Laboratories are responsible for establishing metrological traceability in accordance with this document. Calibration results from laboratories conforming to this document provide metrological traceability. Certified values of certified reference materials from reference material producers conforming to ISO 17034 provide metrological traceability. There are various ways to demonstrate conformity with this document, i.e. third party recognition (such as an accreditation body), external assessment by customers or self-assessment. Internationally accepted paths include, but are not limited to the following.

a) Calibration and measurement capabilities provided by national metrology institutes and designated institutes that have been subject to suitable peer-review processes. Such peer-review is conducted under the CIPM MRA (International Committee for Weights and Measures Mutual Recognition Arrangement). Services covered by the CIPM MRA can be viewed in Appendix C of the BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database) which details the range and measurement uncertainty for each listed service.

b) Calibration and measurement capabilities that have been accredited by an accreditation body subject to the ILAC (International Laboratory Accreditation Cooperation) Arrangement or to Regional Arrangements recognized by ILAC have demonstrated metrological traceability. Scopes of accredited laboratories are publicly available from their respective accreditation bodies.

The Joint BIPM, OIML (International Organization of Legal Metrology), ILAC and ISO Declaration on Metrological Traceability provides specific guidance when there is a need to demonstrate international acceptability of the metrological traceability chain.

3.6 Calibration

3.6.1 Competence in Calibration

Accreditation is formal recognition of testing and calibration competence.

In order for a calibration result to be considered competent, there must be evidence that the laboratory producing it could competently propagate uncertainties from reference instruments to working instruments and to client instruments. Accreditation is the easiest way for a testing laboratory to determine the competence of a calibration laboratory that works for them.

3.6.2 How Calibration affects the Overall Uncertainty of the Measurement

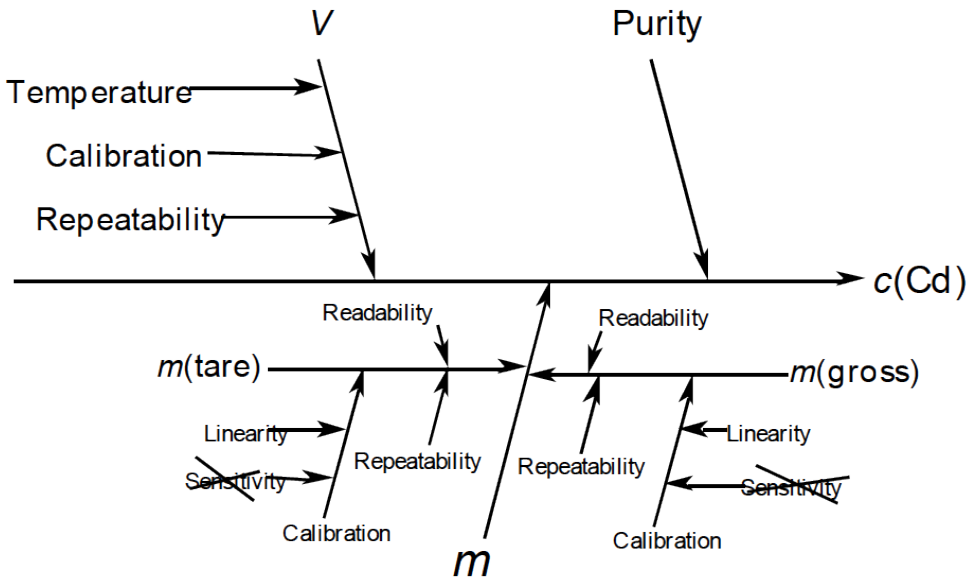
The most comprehensive document that presents information on considering uncertainty of measurement in analytical chemistry is the Eurachem/CITAC Guide CG 4: *Quantifying Uncertainty in Analytical Measurement, Second Edition.* See https://www.eurachem.org/images/stories/Guides/pdf/QUAM2012_P1.pdf.

Of all the uncertainty considerations listed in Section 6 of that document, calibration and metrological traceability affect only one, "Instrument effects." From p 14 of the reference:

> *Instrument effects may include, for example, the limits of accuracy on the calibration of an analytical balance; a temperature controller that may maintain a mean temperature which differs (within specification) from its indicated set-point; an auto-analyser that could be subject to carry-over effects.*

The quote is not entirely correct in that it refers to "limits of accuracy" when accuracy, by VIM definition, is a qualitative concept only. Otherwise, this document contains many examples dealing with methods to consider specific contributors to the uncertainty of a measurement. All of them include consideration of the different steps in the analysis process to assist in estimating the contributors of each of these steps.

A depiction of the set of different considerations can be shown using the fishbone or "Ishikawa" diagram used in the CITAC reference. This specific diagram is drawn from Example A1 – Preparation of a calibration standard.



The diagram is derived from the following algorithm used to determine the concentration of a desired calibration standard of cadmium. The aim is to estimate the uncertainty of the resulting standard solution.

$$c_{Cd} = \frac{1000 \times m \times P}{V} \ (mgl^{-1})$$

where: c_{Cd} is the derived concentration of the calibration standard in milligrams per litre. (The overall uncertainty is sought for this quantity.)
m is the mass of the high purity metal
P is the purity of the metal given as a mass fraction, and
V is the volume of the liquid of the calibration standard

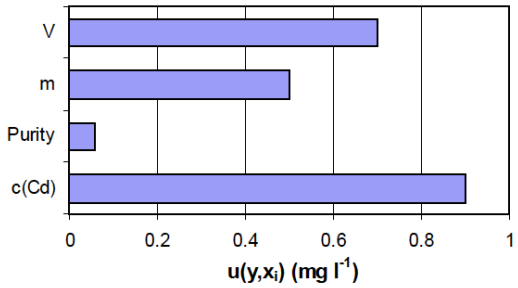
The following expression is used to statistically estimate the uncertainty of the concentration of the calibration standard:

$$u_c(c_{Cd}) = c_{Cd}\sqrt{(\frac{u(P)}{P})^2 + (\frac{u(m)}{m})^2 + (\frac{u(V)}{V})^2}$$

The resulting uncertainty of the standard is shown in the table below.

	Description	Value	Standard uncertainty	Relative standard uncertainty $u(x)/x$
P	Purity of the metal	0.9999	0.000058	0.000058
m	Mass of the metal	100.28 mg	0.05 mg	0.0005
V	Volume of the flask	100.0 ml	0.07 ml	0.0007
c_{Cd}	concentration of the calibration standard	1002.7 mg l^{-1}	0.9 mg l^{-1}	0.0009

The relative size of each of the contributions to this overall uncertainty is shown as:



From the calculations above, it can be seen that the volume of the flask is the single biggest contributor to the overall uncertainty of the concentration. The uncertainty associated with the volume of the flask is, from the Ishikawa diagram above, shown to include:

- calibration of the flask
- temperature of the room/flask
- repeatability of the task of filling the flask.

The certificate provided by the manufacturer quotes a nominal volume with an uncertainty of ±0.1 *ml* for the 100 ml flask. There is no confidence level stated by the manufacturer with this statement and the testing lab can assume a triangular distribution of the values leading to this statement based on the stringence exercised in the normal production of Class A glassware. This makes the uncertainty associated with the calibration MORE optimistic than it would be if the distribution is normal, but without the necessary information, this is the only viable option. The contribution of the calibration to the uncertainty of the flask-filling portion of the process is, therefore:

$$\frac{0.1}{\sqrt{6}} = 0.04\ ml$$

Standard deviations (standard uncertainty) values for the repeatability and temperature contributions to the use of the flask are determined to be 0.02 and 0.05 *ml* respectively (see page 38 of the CITAC reference). The overall uncertainty contribution of the flask (Volume) can be estimated from the square root of the sum of the squares of the three factors; calibration, repeatability and temperature.

This yields:

$$\sqrt{(\mathbf{0.04})^2 + (0.02)^2 + (0.05)^2} = \mathbf{0.07}\ ml$$

As the example is worked through, it is estimated that the overall standard uncertainty of the concentration is 0.9 *mg/l* and that the flask provided the single largest contribution to this estimation. In fact, the calibration of the flask provided one half of the contribution of the flask and about one third of the overall contribution. In accordance with standard practice, this is considered a significant contribution to the overall uncertainty of the measurement.

3.6.3 Using a Traceable (Calibrated) Flask Instead

If the manufacturer of the flask had provided a traceable calibration certificate with the same value, the flask-only expression would be much different. Here, we assume that, since repeatability uncertainties have been demonstrated to be 0.02 ml, direct measurement uncertainties of the flask should be no more than one-half of that, or 0.01 ml.

$$\sqrt{(\mathbf{0.01})^2 + (0.02)^2 + (0.05)^2} = \mathbf{0.05}\ ml$$

The overall standard uncertainty of the final concentration would have been reduced to ±0.7 *mg/l*, instead of ±0.9 *mg/l*, a 20% reduction.

3.7 Internal Calibration

Testing laboratories do not normally have the equipment or the personnel trained in metrology to conduct more than the most basic calibrations. The limiting criterion, on whether or not testing laboratories should undertake internal calibration, is the precision that must be delivered by the working measurement instruments. In other words, if the uncertainty needed by the measurement is finer (smaller) than what a laboratory can deliver in a calibration, then that instrument should be calibrated by an external calibration service provider.

Mass, temperature and volumetric measurement instruments will be discussed in other courses, but simple approaches using the model described above may assist laboratory staff in determining the worth of any internal calibration effort.

3.7.1 Significant Contribution to the Overall Uncertainty of the Measurement.

All instruments providing a significant contribution to the overall uncertainty of the measurement must be traceable and continually monitored for traceability. The default condition for ALL measurement instruments is: Calibration is required every year. There are no exceptions.

If a laboratory can demonstrate that a measurement instrument does not provide significant contribution to the overall uncertainty of ANY of its measurements, it can decide to lengthen the period between calibrations. *Significant contribution* can be determined from the mathematical expressions used to estimate the overall uncertainty. In our example above, the uncertainty of the measurement was the square root of the sum of the squares of the contributors. In such an approach, ***any value that is less than one-third of the LARGEST contributor will tend to zero and will not provide significant contribution.***

In our example above, a calibrated flask would have shown less than significant contribution as proven by any real and actual calibration data of the flask. Calibration contribution of 0.01 *ml* is less than one third of the 0.05 *ml* temperature contribution and it could have been ignored in the expression.

This *Significant contribution* criterion can also be used to help the lab decide on its calibration frequency. If the flask had been competently calibrated, its actual PERFORMANCE (±0.01 *ml*) would have been better than its REQUIREMENT (one third of ±0.05 *ml*), and the laboratory data can demonstrate this difference.

3.7.2 Suggested Criteria for Frequency of Instrument Calibration

If the uncertainty performance of an instrument is smaller than one-tenth of the largest contributor in the estimation of uncertainty for all tests affected by that instrument, then the laboratory has evidence to increase the period of calibration from one to two years or more.

If the uncertainty performance of an instrument is between one tenth (10^{-1}) and one-third of the largest contributor in the estimation of uncertainty for all tests affected by that instrument, then the laboratory has evidence to maintain the period of calibration at around one year.

If the uncertainty performance of an instrument is larger than one-third of the largest contributor in the estimation of uncertainty for all tests affected by that instrument, then the laboratory has evidence to decrease the period of calibration to less than one year

3.7.3 Testing Laboratory Capability

Testing laboratories should not attempt to undertake internal calibration when the desired uncertainties of the calibration surpass laboratory understanding, competence and equipment capability.

The following table provides some guidance on whether or not a testing laboratory should consider doing internal calibration.

Parameter	**Range / Details** **Working Instruments to be Calibrated**	**Uncertainty Required at the Bench**	**Uncertainty which can be obtained from internal calibration**
Temperature (degrees Celsius) Temperature (degrees Celsius) (cont'd)	Single Point for liquid-in-glass thermometers in the 0 to 50 degree range.	±0.2 to 0.5 degrees (microbiology)	**Possible but depends on lab capability**
		±1.0 degrees (all others)	
	-20 to +400 for Thermistors and/or Thermocouples for freezers and autoclaves	±1.0 degrees (all others)	**Not normally possible for testing labs to achieve required uncertainties**
Mass (Gram)	0.1 mg to 1.0 kg balances	±100 ppm (10^{-4}) of specified quantity	**Depends on lab capability**
	Masses (weights) cannot be calibrated in a testing lab	≤ ±100 ppm (10^{-4}) of specified quantity	**Not normally within the capability of a testing lab**
Volume (Litre)	0.1 ml to 100 ml	+/- 1000 ppm (10^{-3}) of specified quantity	**Depends on lab capability**
		≤ ±1000 ppm (10^{-3}) of specified quantity	**Not normally within the capability of a testing lab**

3.7.4 Environmental Factors

The most common requirement for the conduct of competent calibrations is stability of environmental conditions. This is especially true for physical measurement devices such as thermometers, balances and volumetric instruments.

Temperature, humidity, atmospheric pressure, vibration, particulate density (cleanliness), and the acceleration due to gravity variation on the earth's surface can all have some effect on calibrating physical measurement instruments.

Mass: A testing laboratory that wishes to propagate uncertainties for mass must maintain a vibration-free environment, with a reasonable level of humidity (40% - 60%) and temperatures in the area of 20 degrees ± 3 degrees.

Temperature: A testing laboratory that wishes to propagate uncertainties for temperature must be able to maintain a standard ice bath for up to four hours that is deep enough to immerse the bulbs and a great deal of the stem for partial immersion thermometers. Partial immersion liquid-in-glass thermometers are the only thermometers that a testing laboratory should attempt to calibrate, unless special equipment is available.

Volume: A testing laboratory that wishes to propagate uncertainties for volume, must maintain the same environmental conditions as for mass above. The laboratory must also have ready access to distilled water and the air should be relatively free of particulate. Slightly higher humidity may be preferred, in order to reduce sample volume loss during the calibration process.

Chapter 4 – Management System Requirements

4.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **identify** the requirements of a conformant quality system;
- **identify** laboratory approaches in the documenting a quality system;
- **understand** the broad concepts of document control in a laboratory;
- **understand** the requirements for the control of records;
- **understand** the requirements for the use of electronic support to a laboratory (documents, LIMS, e-mail)
- **identify** the approaches to documenting capacity and competence.

4.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 4.1

What should an organisation think about when creating establishing document control procedures? (Select all that apply.)

a. That it protects all documents from modification.
b. That it prevents unauthorised people from making changes.
c. That only appropriate documents are available for use.
d. That the people who work in the organisation can readily use the process of modifying/correcting documents.
e. That the process of creating/modifying/correcting documents does not take too long.
f. That only the top management should authorise new or modified documents.
g. That all documents have approving signatures on each page.

Discussion Activity 4.2

Which of the following document control statements are **TRUE?** (Select all that apply.)

a. All documents are also records.
b. All records are also documents.
c. All documents that are obsolete and removed/archived are records that show conformance to the archival procedure.
d. All forms are documents to control the formats.
e. All forms that have any input information on them immediately become a record.

Discussion Activity 4.3

How does a laboratory examine its own capacity when it receives a new work order or a new sample? (Select all that apply.)

a. No need to worry. It can do everything a client can ask.
b. It determines if it has the technically competent people to do the work.
c. It examines its facilities and equipment to see if they are fit for the work.
d. It checks to see if its document control system is working.
e. It determines if its procedures and quality control/quality assurance will help produce a technically valid result.
f. It checks to see how much the client can afford to pay.

Discussion Activity 4.4

What are the limitations within 17025 on the selection of suppliers of calibration and testing services? (Select all that apply.)

a. Clause 4.6 of 17025 requires a warrantee on all calibration certificates.
b. Clause 5.6 of 17025 requires all instruments used for lab work to be traceable.
c. The VIM definition of traceability includes consideration of competence.
d. If calibration is not on our scope, we can select any supplier we want.
e. Clause 4.5 of 17025 requires competent suppliers for the production of results that affect our own scope
f. We can only use our NMI for calibration services.

4.3 Overview of Basic Management System Concepts (Clauses 5 and 8)

4.3.1 Definitions

ISO 9000 defines "Quality Management System" as:

> "*set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives so as to direct and control an organization with regard to quality.*"

The quality system can be considered to be articulation of the organizational structure, responsibilities, procedures, processes and resources for implementing quality management. While ISO 9000 does not necessarily require documentation for all of these things, ISO/IEC 17025 makes it clear that a conforming laboratory must document everything. Note, that the quality system should only be as comprehensive as needed to meet the quality objectives.

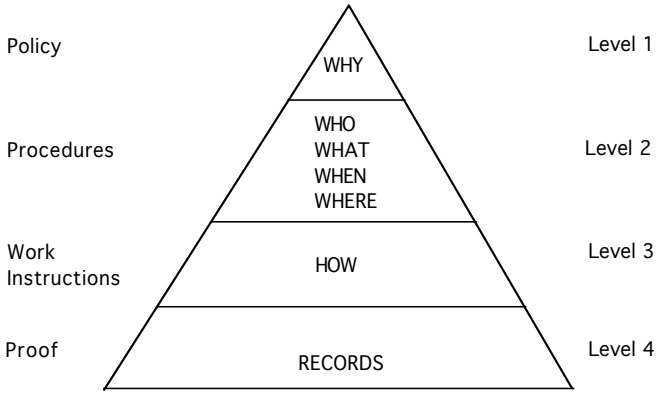
ISO 9000 defines "Quality Manual" as:

> "*document specifying the quality management system of an organization.*"

4.3.2 Representation of a Basic System

From the definitions given above, it is easy to appreciate that a quality system (or quality management system) is really the *who, what, when, where, and how of supporting the laboratory's production of valid results*.

A documented quality system (quality manual and supporting procedures) can also be described as a *set of rules to live by…and how to live by them*, including the organization, functioning and inter-relation of the resources, and policies and procedures necessary to carry out the quality objectives.



Note that these are only two of the many ways of representing a documented and structured quality system. Course participants should not consider these representations as the only acceptable ones, or even the "best" ones.

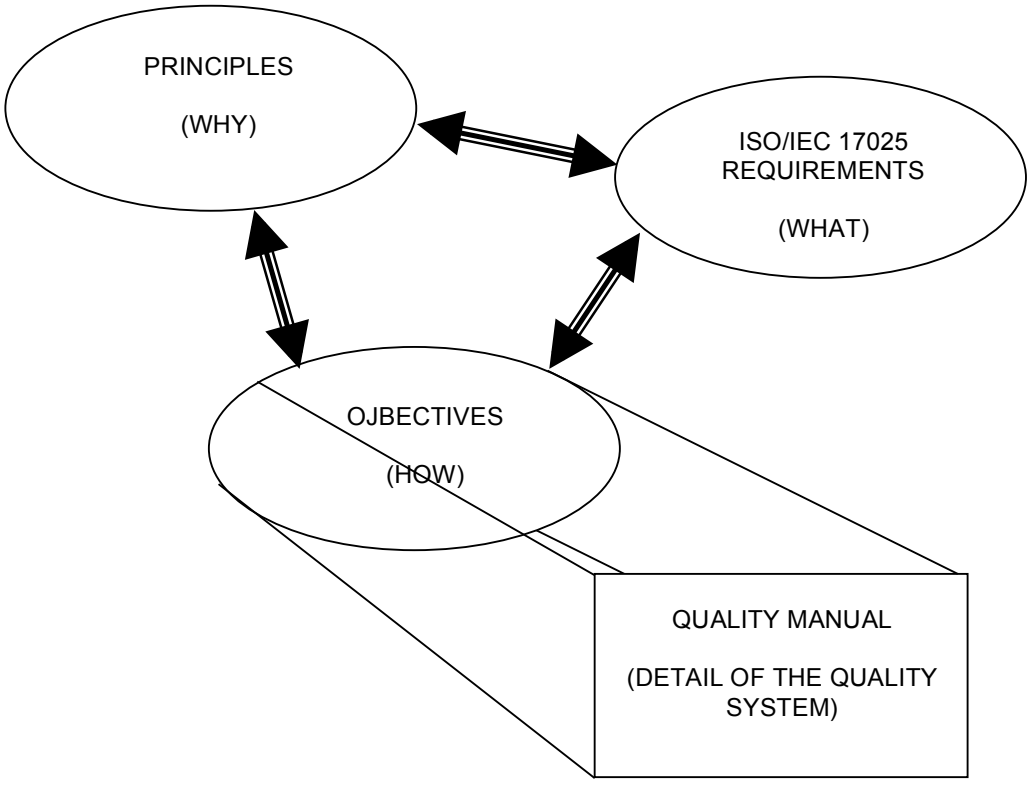
4.3.3 Three Conceptual Approaches in Documenting a Quality System

There are three main approaches to consider in documenting a Quality System that is conformant to ISO/IEC 17025 in a Quality Manual.

- By Requirement. One approach is to simply state the requirements of ISO/IEC 17025 and then document how each requirement shall be met within the laboratory. This approach has the advantage of making use of the exact wording from the standard so as to structure the resulting Quality Manual on the skeleton provided by the standard. Its major failing is a Quality Manual that has been built for assessment and assessors, rather than for use within the laboratory. It is very user-unfriendly.
- By Principle. The second approach is the development of a Quality Manual based on the principles behind the standard. This approach has the advantage of not getting bogged down in the detail during the development of the Quality Manual. Its major disadvantage is that some stated requirements may be missing from the resulting Quality Manual because it may not be obvious that the missing requirement belongs within one or more of the principles.
- By Objective. The third approach is one that focuses on the **effort** required by the laboratory to meet the stated requirements in the standard. This approach makes use of a strategic planning concept called Key Result Areas (KRAs). The resulting Quality Manual starts with broad objectives, the attainment of which allows the laboratory to focus its efforts on implementing acceptable solutions. The one disadvantage to this approach is that some care must be exercises to ensure that **ALL** requirements are covered by the stated objectives.

The best way to understand these three approaches is to appreciate that they are simply different ways of viewing the requirements given in the standard. They are neither mutually exclusive, nor does one naturally fall from another. The requirements remain unchanged, but they can be thought of as either the result of the "principles" or the force behind the "objectives."

The association (linking) of the three concepts can be pictured as follows:



4.4 Inter-relating Objectives, Requirements, and Principles

4.4.1 Making use of the Objectives

Each Section of a laboratory Quality Manual can deal with one specific Quality Objective. A Quality Objective can be given at the beginning of each Section of the Quality Manual. The remainder of each Section would then deal with the policies, procedures, resources, organization and overall effort needed to accomplish that stated objective. This approach focuses the laboratory effort on the individual and collective work required to accomplish each objective.

4.4.2 Cross Reference between the Principles and the Objectives

The following provides an easy cross-reference between the principles behind the standard and the objectives listed in Chapter 2. Beneath each objective are the principles that most apply to the stated objective. The principles are not subordinate to the objectives, but each objective includes some consideration of these associated principles.

- *Implement and maintain a quality system that is documented and incorporates adequate review, audit and internal quality control.*

  Capacity
  Exercise of Responsibility
  Objectivity of Results
  Impartiality of Conduct
  Traceability of Measurement
  Repeatability of Test
  Transparency of Process

- *Adequately train, supervise and demonstrate continuing proficiency of the persons within the laboratory to carry out assigned activities. Establish goals for this objective and track their attainment.*

  Capacity
  Exercise of Responsibility
  Objectivity of Results
  Impartiality of Conduct
  Repeatability of Test
  Transparency of Process

- *Select and validate appropriate test methods (and related work instructions) and incorporate adequate quality control of the methods.*

  Capacity
  Exercise of Responsibility
  Scientific Method
  Objectivity of Results
  Traceability of Measurement
  Repeatability of Test
  Transparency of Process

- *Produce only traceable results, supported by a system of measurement traceable to the SI, through a National Metrology Institute (NMI), and accorded uncertainties appropriate to requirements.*

  Capacity
  Exercise of Responsibility
  Scientific Method
  Objectivity of Results
  Traceability of Measurement
  Repeatability of Test
  Transparency of Process

- *Acquire and make use of facilities, equipment, supplies and services that are appropriate to the work. Ensure they are functioning properly and meet or exceed required specifications.*

  Capacity
  Exercise of Responsibility
  Scientific Method
  Impartiality of Conduct
  Traceability of Measurement
  Repeatability of Test
  Transparency of Process

- *Handle all samples, from reception to disposal, with adequate security, protection of integrity, and defined processes for their receipt, identification, checking, routing, storage and disposal*.

  Capacity
  Exercise of Responsibility
  Scientific Method
  Traceability of Measurement
  Transparency of Process

- *Develop and maintain adequate data management procedures that incorporate appropriate security, recording, calculation, validation, authorisation, transmittal, storage and disposal of all test data and related records*.

  Capacity
  Exercise of Responsibility
  Scientific Method
  Objectivity of Results
  Impartiality of Conduct
  Traceability of Measurement
  Repeatability of Test
  Transparency of Process

- *Manage the workload of the laboratory so as to maintain the ability to produce valid and competent results.*

  Capacity
  Exercise of Responsibility
  Scientific Method
  Transparency of Process

4.4.3 Cross Reference between Requirements of ISO/IEC 17025 and Objectives

This summary table shows the Objectives mapped against the Requirements:

Objectives	**ISO/IEC 17025**
Personnel	6.2 Personnel
Methods	7.2 Methods and 7.7 QC
Traceability	6.5 Traceability and 7.6 Evaluation of Uncertainty
Facilities Equipment and Supplies	6.3-4, 6.6 Supplies, Facilities, and Equipment
Quality system	5 and 8 Quality system
Sample Management	7.3-4 Sample Management
Data Management	7.8 Data Management
Workload Management	8.9.2 l) Workload Management

4.5 Organization, Management, and Management System (Clauses 5 and 8)

This introductory set of requirements in ISO/IEC 17025 deal with the structure and organization of the laboratory. Requirements in 5 include:

- Legal identification of the laboratory and its organization.
- Stipulation to meet regulatory requirements
- The inclusion of “Mobile” and “temporary” facilities.
- The necessity to IDENTIFY and DOCUMENT potential conflicts of interest and how to deal with these

Additional documentation requirements include policies and/or procedures to address specific items in Clause 4.1 – Impartiality and Clause 4.2 – Confidentiality.

Finally, clause 5.7 cites the requirement to ESTABLISH communication processes in the lab and ensure communication takes place regarding the EFFECTIVENESS of the system.

Clause 8 deals primarily with the documented Quality System and its associated Quality Manual. Initially it requires the laboratory to establish an overall quality policy.

4.6 Documentation and Document Control (Clauses 8.2-3)

ISO 9001:2000 requires an organization to produce documentation in only six places. ISO/IEC 17025 requires ALL laboratory policies and procedures to be documented.

The requirements for document control are contained in clause 8.3. The overriding aim for document control is to:

> *All persons who need to use a document in the conduct of their work have access to it and only the most appropriate version of it is available.*

4.6.1 Development, Approval, and Issue of Documentation

Policy and procedure documentation that is developed to meet the aim stated above is best produced when the process used in its development is understood by all staff. It is best conducted by those persons whose responsibilities are aligned with policies and procedures that are the subject of the documentation.

The following are the normal steps that will produce quality system documentation with the least amount of difficulty:

- Identify the persons most responsible for the policy or procedure that is the subject of the document.
- List the requirements of the policy or procedure such as its objective or the objective of any higher level policies or procedures.
- List any factors that may affect the policy or procedure such as scope and related considerations (who, what, where, how, when)
- List the contributors to the policy or procedure (Resources = People, Environment, QC, Procedures)
- Organise these four sets of thoughts into an approach to meet the stated objective. This can be the first draft of the desired policy or procedure.
- Circulate this section to all of the persons responsible for any of the activities given within the document. Seek their consensus. Have them add up the resources required to meet the stated objective (including time).
- Resolve conflicts and produce a second draft.
- Circulate the second draft and develop more consensus.
- Develop the final draft from the consensus established.
- List the documentation requirements of the policy or procedure
- Formalise and document (records) the approval, issue and distribution of the documented policy or procedure.

The simple aim behind the approval process described above is to ensure that the resulting document (policy or procedure) is approved by the appropriate level of authority within the laboratory – and that this same level of authority will continue to exercise responsibility for it by having participated in the decision to develop and issue it.

4.6.2 Maintenance and Modification of Documentation

Whether the document produced is a quality manual, a high level policy, a procedure applicable over the whole organization or a detailed technical procedure focused on a specified narrowly-defined process, it must be distributed to all persons who need access to it for their work. Such distribution can include paper copies or electronic formats, provided that "*only the most appropriate version of it is available."*

Normally, the organization records the location and version of each copy. This can be done using a Master List which can record the location and version of all documents that are part of the laboratory quality system, including external documents that are referenced anywhere in the laboratory quality system.

Amendments to documents can be simplified compared to the formal approval and issue procedure described above, but the results must carry the same level of approval authority and support attached to the original.

Handwritten amendments are also permitted, so long as ALL copies of the amended document are also amended, pending formal modification of a revised version.

When all of the elements of clause 4.3 are in place in a laboratory, it is possible to identify the location and version of all issued documents, conduct amendments, ensure version control, and facilitate appropriate amendments.

4.6.3 Withdrawal and Archiving of Documentation

The easiest way to consider the processes needed to withdraw a document from service is to consider that it is being amended or modified such that it shall no longer be used. Records such as the Master List are modified to indicate that change, just as if it were being amended or updated.

Document and record retention, once a document has been withdrawn, depends on whichever specification is the longest. This may come from a regulatory authority, the Province/State of the laboratory, the Federal Government, or any other specifier, such as a professional association. Whichever is the longest is the one that should be used by the laboratory.

4.7 Records, Record Keeping and Control of Records (Clause 7.5 and 8.4)

ISO/IEC 17025 requires a laboratory to record the results of ALL laboratory activities related to the conduct of their work. The overriding aim for the generation and control of records is to:

> *Produce and control appropriate evidence of the conformant implementation of requirements. In other words, "records" allow laboratories to demonstrate that "documents" have been followed.*

4.7.1 Generation and Retention of Records

The requirements for the control of records are contained in clauses 7.5 and 8.4. Once a record is generated, it is normally controlled the same way as a document, in that it must be stored to protect it from deterioration, unauthorised viewing, and unauthorised amendment.

Records are best produced when the processes used in their development are understood by staff conducting their generation and normally the result of specific recording procedures. These may include specific formats, into which data can be placed to become records. The original controlled formats are part of documents, and only become records when the observed data is inserted into each format.

Records are best generated by those persons whose responsibilities are aligned with the documented procedures containing the controlled recording format.

The simple aim behind the generation process described above is to ensure that the resulting record is generated by the appropriate level of authority within the laboratory – and that this same level of authority can exercise responsibility for the generated record.

4.7.2 Maintenance of Records

Once generated, and the information has been manipulated and used in the production of reports, records are normally stored for future reference. Such storage can include paper copies or electronic formats.

Amendments to records must identify the person (with the authority to make the change) and allow the laboratory to track the original observation through the change and when such change occurred. Handwritten amendments are also permitted, with the same provisos.

4.7.3 Archiving of Records

Unlike documents, records are not "withdrawn" from service. Records are normally archived when the laboratory no longer needs immediate access. When their information is no longer required, they can be destroyed.

The timelines for archiving and destruction should follow the same criteria as for Document Control (8.3). The laboratory should use whichever is the longest specifications that apply from regulatory authorities, Provincial or State regulations, Federal regulations, or any other specifier, such as a professional association.

4.8 Use of IT in Support of Document Control and Control of Records (Clause 7.11)

Many laboratories make use of electronic systems (computers and software - information technologies-IT) that:

- Support the collection of data
- Support the manipulation and reduction of data
- Support the storage, retrieval, amendment, archiving and transmission of data, documents and records
- Support the development of quality system documents and records

4.8.1 General Guidelines

General guidance on acceptable and appropriate methods for making use of IT in support of testing can be found in *Section 10 of the MOTIVA ISO/IEC 17025 Guide*. The following requirements are the most common ones intended from the standard:

- Ensure the continuing integrity of electronic data, documents and records
- Ensure the continuing validation of software
- Ensure the continuing confidentiality of electronic information
- Ensure adequate control and tracking for the amendment of electronic documents, data, and records
- Ensure the continuing retrieval of electronic data, documents and records

The following are the areas that would normally be addressed by electronic system policies and procedures in use at accredited laboratories:

- Integrity and control of electronic data
- Validation of information technology solutions, including software and applications
- Confidentiality/security of information – access control
- Retrieval of electronic data, documents and records
- Maintenance of electronic systems

4.8.2 Integrity and Control of Data, Documents and Records

The integrity and control of electronic data, documents and records may depend on the measures taken for their protection from inadvertent or unauthorized amendment and of their direct correlation to original data, documents, records and observations.

Accredited laboratories should develop and implement procedures to prevent the inadvertent and/or unauthorized amendment of computer software, electronic records, documents and data. The procedures should stipulate the steps to be taken to formally amend computer software, electronic data, documents, and records. [8.2, 8.3, 7.5, 8.4]

- Controlled access to software, electronic records, documents and data.
- Create multiple roles that read-only or read-write.
- Specify the persons who are normally granted access.
- Use of user ID and/or passwords
- Use of read-only storage media
- Clear and simple procedures to modify software, documents, records and data that provide the tracking information for amendments, which normally includes the identity of person amending, date and time of amendment, identity of person approving amendment (if applicable), date and time of approval include the reason(s) for change.
- Back ups of current versions, so as to allow restoration to current condition, if current storage media discontinues normal retrieval access.
- Consider migration of data to new media types during the record retention period.

4.8.3 Validation of Electronic Systems

The validation of computer-based applications is the result of measures taken to validate the ability of the applications to perform as specified. Specifications can vary from simple word-processing applications to complex algorithms in dedicated measurement applications, such as Coordinate Measuring Machines (CMM). The Note in Clause 7.11.2 of ISO/IEC 17025, indicating that validation of commercial off-the-shelf software does not apply to computing applications that are used to collect, manipulate or reduce data. For these types of applications, Clause 6.4.4 governs, because the application is considered to be a piece of measurement equipment, whether or not it was purchased from a commercial vendor.

Accredited laboratories should develop and implement procedures to formally document the validation of computer systems (software and applications) in support of laboratory operations. Such validation should be commensurate with each type of computer-based solution used in the laboratory and its intended purpose and scope. [7.11]

- See paper by Gregory D. Gogates, A2LA Assessor, member EA ad-hoc group on the use of computers, “Software Validation in Accredited Laboratories,” 27 Sep 2001
- Determine the level of validation required for the electronic system (hardware, firmware, or software, or parts of all of them) from its classification as either Commercial, Commercial-user-modified, User-developed.
- Document the validation process used. See Figure 3 of “Software Validation in Accredited Laboratories.”
- Monitor the continuing validation of the electronic system throughout its life cycle in the laboratory. See Figure 1 of “Software Validation in Accredited Laboratories.”

4.8.4 Confidentiality/Security of Information – Access Control

The security of software and electronic information, regardless of its configuration as data, records or documents, is the result of measures taken to protect it from unauthorized access, viewing and dissemination.

Accredited laboratories should develop and implement procedures to provide adequate protection for software, electronic records, documents and data in order to prevent access and viewing by unauthorized persons. Such protection should be commensurate with each type of record, document or observation/data point collected, stored, or maintained by the laboratory. [8.2, 8.3, 7.2, 7.5, 8.4]

- Controlled access to software, electronic records, documents and data.
- Specify the persons who are normally granted access.
- Use of passwords or “digital signatures.”
- Tracking of access to software, electronic records, documents and data

- Use of increased levels of security, such as Public Key Infrastructure (PKI), or other types of encryption, in the transmission and receipt of electronic records, documents and data.
- Use of "firewalls" to control external access
- Assurance that electronic-signatures are permanently linked to specific instances of data.

4.8.5 Retrieval of Electronic Data, Documents and Records

The retrieval of electronic data, records or documents, is a continuing measure of its availability, both during and after its use within the laboratory.

Accredited laboratories should develop and implement procedures to provide adequate facility for the continuing retrieval of electronic records, documents and data in order to permit access and reference to such records, documents and procedures for as long as the laboratory may require such access and reference. [7.5, 8.3, 8.4]

- Off-site storage
- Use of formats that are likely to be used in the future such as Adobe Acrobat (*.pdf) format or XML format or ASCII format.
- Use of media that are likely to be used in the future such as CD-ROM
- Ensure migration of data when it needs to be transferred to new media.
- Use of an appropriate method of indexing archived data to facilitate ease of retrieval

4.8.6 Maintenance of Electronic Systems (Computers/Software)

The maintenance of electronic systems (software and applications) in a laboratory is a measure of the ability of the laboratory to monitor the performance of all of the components of the electronic system and effect preventive and corrective actions on their use.

Accredited laboratories should develop and implement procedures to affect the maintenance of electronic systems (software and applications), which may include software, firmware and/or hardware, to prevent non-conforming operation of the electronic system. [5.5] See paper by Gregory D. Gogates, A2LA Assessor, member EA ad-hoc group on the use of computers, "*Software Validation in Accredited Laboratories,"* 27 Sep 2001

- Operation by trained and qualified personnel
- Preventive maintenance schedules for hardware.
- Document the validation process used. See Figure 3 of "Software Validation in Accredited Laboratories."
- Monitor the continuing validation of the electronic system throughout its life cycle in the laboratory. See Figure 1 of "Software Validation in Accredited Laboratories."
- Inclusion of electronic systems within laboratory calibration program, as required.
- Identification of triggers to re-validate that define when re-validation needs to occur and the level of detail required.

4.9 Documenting Capacity and Competence

4.9.1 For the Laboratory (Clause 7.1)

Competence is defined in Section 1.3.4 from ISO/IEC 17024 as the: "*demonstrated ability to apply skills and knowledge.*"

Whenever a laboratory receives a request to take on new work, or whenever it receives a new sample for testing or calibration, ISO/IEC 17025 has laid out requirements for the laboratory to examine its own capacity and document any decisions it makes regarding the acceptance of the new work or the sample.

Clause 7.1 details the considerations to document, but they can be boiled down the first principle behind the standard – CAPACITY. See Section 1.5.1 above.

> *Concept that a laboratory has the resources (PEOPLE with the required skills and knowledge, the ENVIRONMENT with the required facilities and equipment, the QUALITY CONTROL, and the PROCEDURES) in order to undertake the work and produce COMPETENT results.*

This examination can be documented in many ways, and some laboratories make it a mechanical exercise carried out by the receiving clerk. They will accept samples only for tests that are listed on the published scope of accreditation. This is a simple approach, but can limit business somewhat.

Alternatively, a laboratory may institute a method of recording that someone with the competence and authority to make the decision in the laboratory has done so. This can be as simple as a short checklist on a piece of paper that signifies that the person believes that the laboratory does have:

- the people with the requisite skills and knowledge,
- the environment with the requisite facilities and equipment,
- the requisite quality control, and
- the requisite procedures

…..to produce valid results for the sample submitted or the test requested.

4.9.2 For the Laboratory's Suppliers (Clauses 6.6)

Determining competence for the laboratory's suppliers can be accomplished by drawing the relevant parts from Clause 6.6 of the standard.

Clause 6.6 is about asking an organization that has demonstrated equivalent competence to undertake work for which you are deemed competent. That is the only reason why a laboratory would subcontract work. If the work is NOT on the laboratory's scope of accreditation, it can be treated as purchasing of a service under 6.6.

If a laboratory is accredited, it MUST subcontract accredited tests only to other accredited laboratories – no exceptions. If the test is not an accredited test, then the provisions of Clause 6.6 apply.

Clause 6.6 is also about asking an organization that has met some other qualification so as to deliver goods and services to you THAT MAY AFFECT THE QUALITY OF YOUR TEST RESULTS. This capitalised consideration is the heart of Clause 6.6. If the desired product or service has absolutely no bearing on the quality of test results, then it is not covered by this clause. For example, the supplier of lead pencils in an electronics testing laboratory is in no way crucial to the results produced by the laboratory. This is not true for the supplier of a spectrum analyser in the same lab.

Chapter 5 – Continual Improvement Requirements

5.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **identify** laboratory approaches in recognizing NCs and OFIs;
- **understand** the concepts of corrective and preventive action;
- **appreciate** the importance of internal audit and management review;
- **appreciate** the most effective methods for implementing continual improvement

5.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 5.1

Which of the following are appropriate approaches in implementing continual improvement? (Select all that apply.)

a. Allow all persons in the lab to identify non-conforming and potentially non-conforming issues.
b. Ensure that blame is properly placed.
c. Document all actions in the continual improvement processes.
d. Determine the need for full corrective or preventive action instead of simple remediation.
e. Implement the solution that addresses the root cause.
f. Implement corrective and preventive action for all NCs.
g. Follow up to determine the effectiveness of remediations.

Discussion Activity 5.2

Which of the following are process components of continual improvement? (Select all that apply.)

a. Feedback from customers, complaints and complements.
b. NCs raised from employee performance reviews.
c. PT/ILC outliers.
d. Findings from internal audits and external assessments.
e. Management review determinations.
f. Workplace accidents.
g. Technical work in the lab.

Discussion Activity 5.3

What are the differences and similarities between corrective action and preventive action? (Select all that apply.)

a. Preventive action, unlike corrective action, does not require root cause analysis.
b. They are exactly the same, except for when the original issue occurs.
c. Corrective action is for all issues.
d. Preventive action is only for OFIs
e. Preventive action does not require follow up for effectiveness.

5.3 Overview of Basic Concepts

5.3.1 The Purpose of Continual Improvement

If perfection in a testing laboratory were to be described, and perfection was based on the principles behind ISO/IEC 17025, the description would probably look like this:

"We produce consistent results, day after day, within the 95% confidence region at the specified uncertainties."

Drawing by Iutta Waloschek.
From the website of the University of St. Andrews, Scotland.
http://www-gap.dcs.st-and.ac.uk/~history/PictDisplay/Einstein.html

This attitude, the inherent dedication to the science and the apparent lack of flash and colour in the person making the statement are the very characteristics that engender trust in the work of a laboratory. In other words, this is a PERFECT lab – and 5% of their results may still be outliers.

Continual improvement is always difficult for someone to understand when the objective is not well explained. What is the objective of continual improvement? ISO 9000 tends to imply that there some state of perfection that is the objective for continual improvement. Not so for ISO/IEC 17025.

ISO/IEC 17025 is about only one thing – laboratory competence. Laboratories that have implemented a quality system that conforms to ISO/IEC 17025 should be able to produce valid results…but to what degree, or level?

The authors of ISO/IEC 17025 envisioned laboratories to be able to consistently produce results at specified uncertainties, within the 95% confidence region, day after day after day after boring day. In the world of laboratories, boring stability means TRUST. This can be considered the state of perfection for a testing lab – or the goal of a continual improvement program.

The thing that most commonly interferes with a laboratory's ability to attain this state of perfection is change: change in personnel, change in structure, change in equipment, change in procedure, change in environment etc. The thing that best supports attaining such a state of perfection is stability.

No one can prevent change. However, standards like ISO/IEC 17025 can help us manage it. It provides a systematic method of identifying and addressing those things that would bring about some change and eventually impede the consistent production of valid results. In a good laboratory, continual improvement is mostly about the management of change. An organization may have other goals for their continual improvement program, but these are over and above what the laboratory needs for its own purposes.

Remember that the standard addresses itself to testing and calibration laboratories…those that work in the 95% confidence region. It is not aimed at those that work in the other 5%, such as research labs that are attempting to advance science.

Therefore, the aim of continual improvement in a testing laboratory is:

> ***"To consistently produce results at specified uncertainties, within the 95% confidence region, day after day after day after boring day."***

It is also important to understand that the tools in ISO/IEC 17025 can be used by the laboratory to exploit improvements, which start with root cause analysis.

5.3.2 Definitions

ISO 9000 defines "*non-conformity*" as "*non-fulfilment of requirement*."

The non-fulfilment of specified requirements can be:

- failure of resources to meet either performance requirements or other specified requirements
- failure of organization to comply with documented policies and procedures or work instructions
- failure of test data to meet required standards; i.e.
  - failure to meet all conditions necessary to ensure the integrity and representativeness of the sample (i.e. sample history deficiencies exist)
  - failure to comply with the test method and supporting work instructions
  - failure in method performance as demonstrated by results provided by QC samples
  - inherent property of the sample that compromises testing (e.g. as verified by method of standard additions); and
  - relevant evidence as provided by data validation. (e.g. as a result of comparison with expected values, ranges or relationships).

5.4 Identifying NCs and OFIs

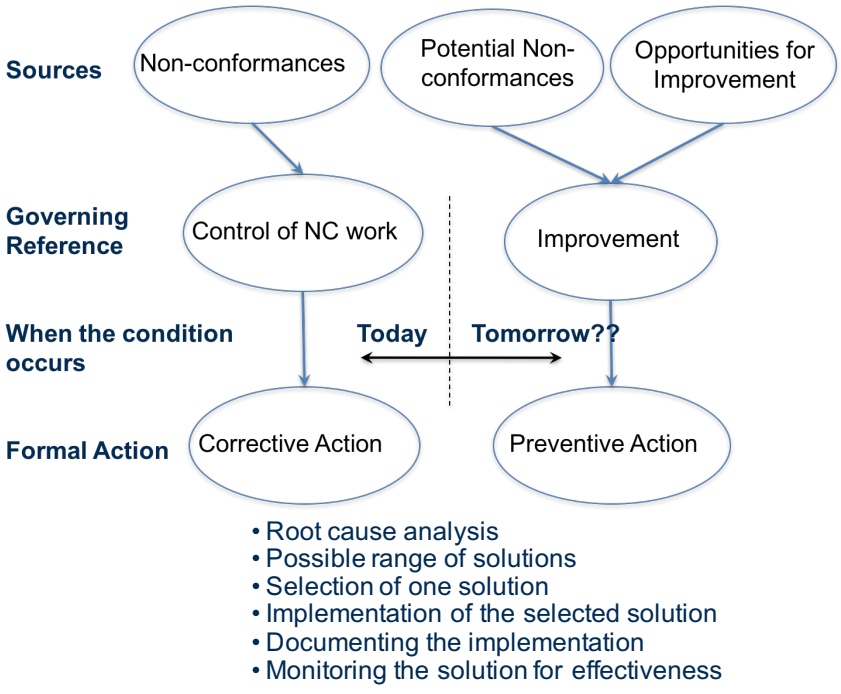
ISO/IEC 17025 contains seven (7) clauses that facilitate our ability to find these "NCs." They are:

8.6 – Improvement (including Feedback)
7.9 – Complaints
7.7 – Quality Assurance / Quality Control
8.5 – Actions to address risk and opportunities
8.7 – Corrective Action
8.8 – Internal Audits
8.9 – Management Review

All of these clauses provide some direction on the search for NCs. Because ISO/IEC 17025 is not a perfect document, it neglects to specify that these same clauses can also be used to search for "PNCs" as well. In fact, it dedicates an entire clause on what to do when a non-conformance is discovered (identified). It has only recently included wording on what to do when a "PNC" is discovered.

The clauses cited above are the best sources of procedures against which non-conforming and PNC (OFIs) can be identified and raised.

Laboratory policies and procedures written against these clauses provide the best means of identifying circumstances that should be considered under continual improvement.



The unique clauses are those dealing with feedback and service to the customer, because they may require the laboratory to undertake work to determine whether a situation is conforming or not, before any

identification is made. In other words, an investigation into the validity of feedback is necessary in order to determine whether a circumstance is non-conforming (or potentially non-conforming).

5.4.1 Feedback is about Perception (Clause 8.6)

One of the requirements in ISO/IEC 17025 is to actively seek the feedback of laboratory customers and do something with it to improve the management system and the technical activities. These are ambitious words.

What does this mean to a lab? Or to any organization that is contemplating the use of an active feedback system? Simply put, it means that the organization has to implement some method of collecting data on how their customers feel about the services they use, the treatment they receive, the interactions they experience and the expectations they take into their relationship with the organization.

How do the laboratory customers feel about the service and the methods used by the laboratory to interact with their customers? How do they feel about the way the laboratory treats them, or whether their expectations are being met? From the way these questions are worded, it is clear that feedback is generally used to measure perception – customer perception of the laboratory, the organization, the laboratory staff, and the work of the laboratory.

5.4.1.1 Examples of Feedback from MOTIVA

If ISO/IEC 17025 calls for this sort of activity explicitly, and MOTIVA trains laboratories against this standard, it might be useful for laboratories to appreciate how MOTIVA has been acquiring and using feedback.

Most North American assessors and the labs they assess are familiar with the feedback provided at the end of an assessment activity. In some accreditation bodies, all laboratory responses are collated into one document and submitted to top management as part of the measurement metrics of the accreditation program. These can be fairly large documents.

Most accredited PT programs routinely asks their participants to comment on specific aspects of program delivery, including any training and workshops held to openly discuss issues.

MOTIVA Training Inc's web page (https://motiva-training.com/index.php/about-us/feedback-and-testimonials) is dedicated to publishing feedback from all participants who have taken training – the good and the bad. This web page includes feedback received from participants who have taken training from MOTIVA staff even before there was a MOTIVA.

5.4.1.2 Making use of the Information Received

MOTIVA's very visible methods of feedback are used to modify goals, objectives, approaches and delivery methods in MOTIVA's delivery and content and that is what ISO/IEC 17025 is looking for laboratories to do with their own feedback mechanisms. Feedback systems can deliver valuable information to laboratories in real time. In good organizations, feedback can have constant, appreciable, and relevant impact on what is done, and how it is done. This approach is in line with best practices in continual improvement and is the main reason why the 2005 version of ISO/IEC 17025 now includes a requirement for active acquisition of customer feedback.

What are the potential immediate effects of all this feedback on the organization collecting and using it? For a laboratory, it would mean increased use of current data to affect the direction and methodologies of the laboratory – and less use of "that is how we have always done it." It should not affect the underlying scientific method in any test or calibration, but it may affect the supporting procedures and the customer interaction processes.

Feedback can also be used to identify external support for the direction of an organization and its delivery of product or service – sort of a marketing tool. However, organizations that collect, use and publish feedback may be disappointed because most of their customers will never read or be influenced by this published feedback. Such is also MOTIVA's experience. It may be surprising that customers rely so little on what other customers may have to say about the organization or the laboratory. For example, only one in 50 MOTIVA Training Service participants admit to visiting the MOTIVA training feedback site to review what others have said about us before they purchase training. So the real advantage of feedback

is not the more obvious "pat-on-the-back" from customers. It is the contribution made to improving services and delivery.

5.4.2 NCs, PNCs and Improvements (Clauses 8.5, 8.6 and 8.7)

These two clauses capture most of the instances of conditions in the laboratory that have (or may) impede the consistent production of technically valid results. The processes for capturing both identified NCs and PNCs can be the same…same procedures, same forms, and same approach. The only stipulated difference is Time.

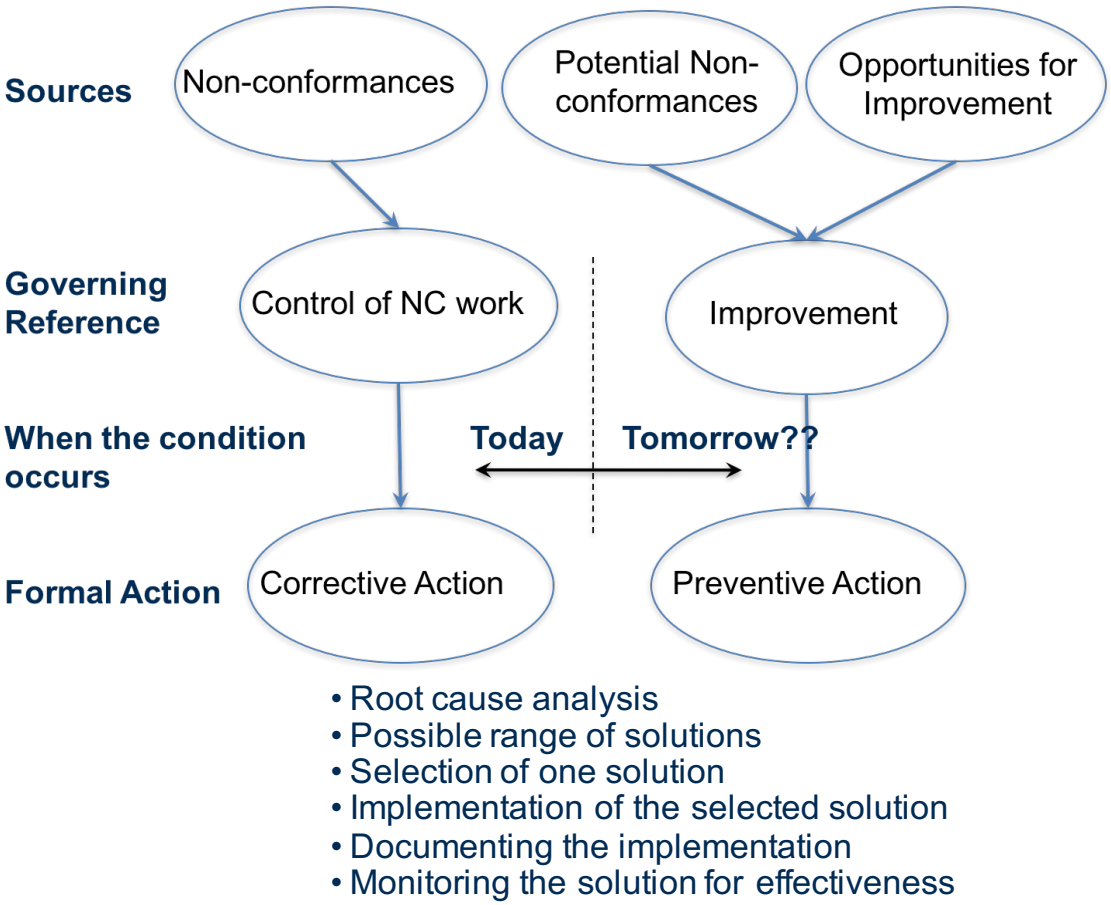
5.4.3 Internal Audit & Management Review NCs, PNCs and OFIs (Cl 8.8, and 8.9)

Internal audits and management reviews are effective ways to recognize and identify conditions that have (or may) impede the consistent production of technically valid results. Internal audits provide the best indication of the health of the quality system and both these clauses are covered in the Chapter 4 – Monitoring and Measuring the Quality System.

5.4.4 Quality Control activities within the laboratory (Clause 7.7)

This clause details the actions that a laboratory must undertake to ensure the fitness for purpose of its methods and technical activities. This activity is a very good at identifying NCs and PNCs directly related to technical work.

5.5 From Identification to Action in Continual Improvement



5.5.1 What does this mean to the lab?

The processes for capturing both identified NCs and PNCs can be the same…same procedures, same forms, and same approach. The only stipulated difference is Time.

The processes for addressing both identified NCs (corrective action) and PNCs (preventive action) can be the same…same procedures, same forms, and same approach. The only stipulated difference is Time.

All personnel can now participate more effectively in identifying PNCs. They understand them better and they are more certain about which is which.

Implementing this approach in a formal manner also allows the laboratory to pro-actively implement continual improvement.

5.6 How to Implement Continual Improvement in a Lab

This is the formal method of treating NCs and PNCs/OFIs in a laboratory quality system.

Corrective Action or Preventive Action (CAPA = Continual Improvement)

- Root cause analysis
- Determine a range of potential solutions
- Select one
- Implement the selected solution
- Document the implementation

} These two alone are only **Correction** or **Prevention**.

- Monitor the implemented solution for effectiveness

5.6.1 Correction and Prevention

Correction and prevention are the simplest actions to take and they involve only the implementation and documentation of a solution that does not involve root cause analysis.

5.6.2 The Need for Corrective or Preventive Action

Whenever NCs, PNCs or OFIs are identified, the laboratory may normally address them in one of two ways:

- Correct/prevent the problem by implementing a solution and documenting both the problem and the solution. This is known as correction or prevention and should not be confused with corrective- or preventive-action.
- Complete full corrective- or preventive-action, commencing with root cause analysis.

The decision to select either approach should normally be done by asking three questions and determining, from the answers, which is the most appropriate approach – simple correction/prevention or full-fledged corrective- or preventive-action.
The three questions are:

- Does the condition cause the laboratory to produce invalid (incorrect results)? Or could it?
- Does the condition present the laboratory with unacceptable risk to the lab or to people, such as health and safety concerns?
- Will it be easier to conduct full corrective or preventive action than simple recurring correction or prevention?

Full corrective- or preventive-action with root cause analysis is required only if any of these three questions are answered with a "yes." Otherwise, the situation has little impact on the laboratory, its people, its visitors, or its ability to consistently produce technically valid results. It is easier to continually correct the situation and no root cause analysis is required.

5.6.3 A Holistic Approach

ISO/IEC 17025 is focussed on a laboratory's ability to produce valid results, and NCs can be thought of as those circumstances that prevent this. Corrective and Preventive action, therefore, can be thought of as those activities which mitigate the adverse effects of NCs – today and tomorrow.

If we understand that PNCs are only the identification of a POTENTIAL or POSSIBLE non-fulfilment of specified requirements, then it becomes much easier to determine the best solution.

What can be done to address both NCs and OFIs/PNCs? They can be dealt with using the same formal process for corrective- or preventive-action.

- Understand that a NC is different from a PNC in only one aspect - Time.
- Understand that the laboratory quality system needs to address both of these sets of circumstances.
- Understand that NCs can be dealt with by simple correction or undertaking the more formal process of corrective action.
- Understand that PNCs can only be dealt with using the more formal preventive action – more about this later.
- Understand that a corrective action differs from a preventive action in only one aspect – Time. The latter is to prevent the first time occurrence of a non-conformance while the former is to prevent recurrence of one that has already occurred.

ISO 9001 describes the whole process of continual improvement as having the following steps:

- identifying NCs and PNCs
- determining the need to prevent occurrence of PNCs or recurrence of NCs
- determining the causes of NCs
- determining and implementing the action that is needed
- recording the results of the action taken
- reviewing the action taken (monitoring for effectiveness)

Compare this list with that shown at the bottom of the bubble diagram in the section "*From Identification to Action"* above. They are nearly identical. This is once instance where the concept presented in ISO 9000 provides a better model for laboratories to follow, than simple interpretation of the wording in ISO/IEC 17025 clauses 8.5, 8.6, and 8.7.

The laboratory can now formally document its continual improvement goals, processes, procedures and forms by simply pointing to its own efforts in corrective and preventive action.

5.6.4 Defining the "Root" Cause

The first step in the conduct of either preventive or corrective action is an analysis of the root cause. Root causes are the reason that a non-conformance or potential non-conformance came to exist in the first place. In order to permanently eliminate the adverse condition – its root cause must be identified and then addressed/eliminated.

Organisations often treat non-conformances as "errors" when they are only indications that the quality system is not adequately supporting the work of the people within the system. It is the quality system that needs to be corrected, in most instances – not people.

At the point of discovery of a non-conformance, or a potential non-conformance, the best approach to take is to recognise that the root of the non-conforming condition is that something is "missing" from the basic list of:

People:

- *With the required skills, and*
- *With the required knowledge,*

The Environment:

- *with the required facilities, and*
- *with the required equipment,*

The Quality Control/Quality Assurance, and

The Procedures

in order to undertake the work and produce technically valid results.

This list provides us with a number of "categories" of root cause and we can select the most appropriate of these as our first approximation of the actual root cause. They are:

- Personnel Factors dealing with the demonstrated skills and knowledge of the persons involved.
- Environmental Factors dealing with the physical plant, facilities, and equipment.
- Quality Factors including quality control and quality assurance, and
- Procedural Factors including the basis and validity for the work being executed.
- *Organisational Culture (????)*

Sometimes an organisation can have all of these things in place and still have difficulties. The most common cause for this condition is its leadership and the organisation culture that emanates from the leadership. Organisational culture and leadership are, therefore, the final category for root cause considerations.

There is a catch to this final category, however. If the root cause of a non-conformance can be traced back to something missing in either the culture or leadership of the organisation, it may be very difficult to have this root cause accepted.

5.6.5 Creating Solutions that Endure

Once the actual root cause of the non-conforming condition has been determined, the work in developing solutions (corrective / preventive actions) must focus on eliminating the root cause.

Corrective action is aimed at preventing recurrence of an identified non-conformance. Preventive action is aimed at preventing the first-time occurrence of a potential non-conformance.

Examining the approach described above, the determination of root cause is most appropriately followed by the identification of a set or spectrum of solutions – any of which will address the root cause. This

The actual selection of the corrective / preventive action solution, however, is entirely dependent on others and their input. Solutions implemented in isolation do not last. They do not consider how people, other than ourselves, work within the quality system and they cannot support people in their implementation of the quality system. The same, or similar, non-conformances may occur again.

The most appropriate approach for the selection of the corrective / preventive action address the actual root cause and endure. This approach involves the development of consensus within the group expected to implement selected corrective / preventive action. Consensus makes the solution stronger and allows others to identify problems and take preventive action as similar conditions are encountered following implementation. These types of solutions endure and prevent recurrence of non-conformances.

Organisations attempting to develop systematic approaches in this area should consider the following steps:

1 Develop a set of potential solutions, all of which address the identified root cause,
2 Determine the solution that best meets the needs of those affect by the root cause condition and those that will be required to implement it. Develop consensus.
3 Select the solution agreed by all.

5.6.6 Documenting the Effort from Root Cause to Solution

A comprehensive quality system works best when the laboratory treats non-conformances and potential non-conformances in a congruent fashion, understanding these two are the same – except for the time of their occurrence.

Accepting this, the records created for one, can also use the same format as the other. The sample provided in this lesson can be used for any non-conformance leading to corrective action, any potential non-conformance leading to preventive action and any opportunity for improvement leading to preventive action.

5.6.7 Monitoring Solutions, Follow up and Timelines

Clause 8.7 of ISO/IEC 17025 requires the monitoring of corrective actions to ensure that, at some later date, the laboratory is able to determine that a particular corrective action has eliminated a root cause.

These monitoring and follow-up activities are required to complete the corrective action and preventive action processes. Best practice in continual improvement for corrective and preventive action therefore includes a mechanism for tracking monitoring and follow-up.

Monitoring and follow up is aimed at a formal consideration of the effectiveness of implemented corrective and preventive actions. The simplest method of doing this is to set a date, at some time in the future, to examine the condition to see if the corrective action has effectively eliminated the underlying root cause.

This method provides semi-automatic triggers to bring the issue forward at some time in the future – and can be well supported by database applications.

Chapter 6 – Monitoring and Measuring a Lab QMS

6.1 Learning Objectives

Upon completion of this chapter, you should be able to:

- **appreciate** the requirements for internal audit and management review;
- **identify** the areas of the laboratory that must undergo internal audit;
- **identify** the considerations that must be part of management review;
- **understand** how to close out and follow up findings from all sources.

6.2 Completing the Chapter

Consider the following questions. Discuss your findings and those of others in your group. This can be done by seeking clarification of others, providing support to others where required and challenging responses when necessary.

Discussion Activity 6.1

What are the requirements for the frequency of internal audit? Which documents govern?

a. Our accreditation body policies require us to conduct internal audits once per year.
b. The standard requires internal audits to be conducted once per year. See 4.14.1 Note.
c. There are no formal requirements for the frequency of internal audits.
d. APLAC TC 002 forces our accreditation body to require yearly internal audits from us.

Discussion Activity 6.2

What are the requirements for the frequency of management review? Which documents govern?

a. Our accreditation body policies require us to conduct management review once per year.
b. The standard requires internal audits to be conducted once per year. See 4.15.1 Note.
c. There are no formal requirements for the frequency of management review.
d. APLAC TC 003 forces our accreditation body to require yearly management review from us.

Discussion Activity 6.3

What are the benefits of internal audits? (Select all that apply.)

a. Internal audit tells us who has made mistakes.
b. Internal audit allows us to check the competence of our people.
c. Internal audit is the best means to determine if our quality system is helping us produce valid results.
d. Internal audit tells us if our system is: implemented, effective, and allows for improvement.

Discussion Activity 6.4

How does management review allow the laboratory to measure itself? Against what is the measurement conducted? (Select all that apply.)

a. Management review allows top management to allocate responsibility.
b. Management review tells top management if the system supports our corporate objectives.
c. Management review tells the staff how the laboratory should be managed.
d. Management review is about who gets bonuses.

6.3 Overview of Basic Concepts

6.3.1 The Need for Measurement

When an organization wishes to see how well an instrument is performing, it is submitted for calibration. Its ability to measure is compared to another instrument of known measurement ability. This comparison is called calibration.

The same approach applies to a laboratory quality system. In order to determine if the quality system is performing as required, it must be measured. This measurement is generally in the form of an internal audit.

Normally, internal audits have two specific goals.

- The first is to measure the effectiveness of the system to determine if it conforms to requirements and adequately supports the ability of the laboratory to produce technically valid results.
- The second aim of an internal audit is to determine if the system allows people to identify PNCs and OFIs.

An internal audit is the best tool an organization can use to determine how well the quality system is functioning, but it is only one of the inputs placed before top management in monitoring how well it supports the operations of the organization.

ISO/IEC 17025 separates these measurement and monitoring functions into two clauses, 8.8 – *Internal Audits* and 8.9 – *Management Review*. Note that an internal audit and an external assessment have very different aims.

- An external assessment is to determine the competence of the organization to produce technically valid results and concentrates on the requirements of the standard.
- An internal audit concentrates on the requirements articulated in the organization's own quality system.

6.3.2 International Requirements

In North America and throughout the Pacific Rim nations, assessment of laboratories is restricted by the distances involved. The assessment cycle of accreditation bodies in these areas is two years. In Europe, it is generally one year.

This difference prompted the Asia Pacific Laboratory Accreditation Cooperation (APLAC), a regional body with a mutual recognition arrangement (MRA) to create two requirements documents relating to the frequency and content of internal audits and management reviews. These documents are:

- APLAC TC002 – *Internal Audits for Laboratories*, and
- APLAC TC003 – *Management Review for Laboratories*

These documents specify the period of both internal audits and management reviews as being one year. This is because accreditation bodies signatory to the MRA will not visit accredited labs more frequently than once every two years, under normal circumstances. In the intervening years, accredited laboratories are expected to, at the very least, conduct their own system measurement and monitoring.

6.4 Internal Audit (Clause 8.8)

The definitions for "audit" are given in the MOTIVA ISO/IEC 17025 Guide published on the MOTIVA website and these are quite informative for a professional in the field of auditing or assessing, but they are not very useful for a staff that is expert in other things.

In essence, an internal audit, like all types of audits, is a comparison of what is required to what exists. This comparison is based on the gathering of "objective evidence" of current conditions and situations. This objective evidence is gathered by:

- Document review
- Observation

- Interview

Contrary to popular belief, there is no “good” or “bad” result from an internal audit. There is only the objective aspect of “meeting requirement” or “not meeting requirement.” All results are “good” results, even those that demonstrate the existence of a condition that does not meet the stated requirement. Such a result gives valuable information in order to correct or improve processes. It allows top management to do their job.

Top management:

- Are the owners of this process,
- Sell the requirement for internal audits to the staff,
- Approve the internal audit program and plan,
- Facilitate implementation of the requirement (remove obstacles for its accomplishment),
- Provide the Quality Manager with sufficient levels of responsibility to develop and, upon approval, implement the plan,
- Approve solutions resulting from the process, and
- Monitor the continuing effectiveness of the process.

An organization that seeks detailed knowledge about how well it is doing its own business is headed in the right direction. Such an organization is well led and not afraid to ask itself the hard questions.

In good organizations, the normal role of staff in internal audits is:

- Participate in the process, including the planning stages.
- Promote its benefits (if understood).
- Propose solutions when non-conformance / OFI challenges are encountered.
- Implement corrective action solutions when approved.
- Maintain the quality system as specified.
- Actively seek out OFIs.
- Make use of the benefits of the process.

The following are some of the considerations to be examined and addressed when planning and implementing internal audit programs in laboratories:

- Auditing is a “formal” process. Take no shortcuts. This ensures that all parties are treated with respect.
- The process selected must be one that can be successfully implemented. Time and resources are key.
- Avoid undue costs. Recognize the real benefits. Promote the positive aspects.
- Avoid the damage (hidden costs) of staff perceiving “failure” because of the audit process. This is a leadership challenge, but it is critical to the success of the program.
- Shorter, and more frequent, audits reinforce the requirement to maintain the quality system and result in fewer NCs. Longer and less frequent audits cost less in time and personnel.
- Quality documentation must be in place for an audit to take place. This includes:
    - Quality manual
    - SOPs
    - Test/Calibration Methods
    - Supporting Records

6.5 Management Review (Clause 8.9)

One role of top management is to carry out regular systematic evaluations of the suitability, adequacy, effectiveness and efficiency of the quality management system with respect to the quality policy and quality objectives. This review can include consideration of the need to adapt the quality policy and objectives in response to changing needs and expectations of interested parties.

The review includes determination of the need for actions. Amongst other sources of information, audit reports are used for review of the quality management system.

This activity demonstrates and documents top management commitment to monitoring the quality system and its implementation.

Management review can also introduce any necessary changes or improvements; such as:

- organizational changes,
- hiring additional staff,
- providing specialised training,
- modifying the services offered,
- purchasing additional equipment, and
- modifying existing policies and procedures.

Section 8.9 of ISO/IEC 17025 states:

> *"**8.9.3** The inputs to management review shall be recorded and shall include information related to the following:*
>
> *a) changes in internal and external issues that are relevant to the laboratory;*
> *b) fulfilment of objectives;*
> *c) suitability of policies and procedures;*
> *d) status of actions from previous management reviews;*
> *e) outcome of recent internal audits;*
> *f) corrective actions;*
> *g) assessments by external bodies;*
> *h) changes in the volume and type of the work or in the range of laboratory activities;*
> *i) customer and personnel feedback;*
> *j) complaints;*
> *k) effectiveness of any implemented improvements;*
> *l) adequacy of resources;*
> *m) results of risk identification;*
> *n) outcomes of the assurance of the validity of results; and*
> *o) other relevant factors, such as monitoring activities and training.*
>
> ***8.9.3** The outputs from the management review shall record all decisions and actions related to at least:*
>
> *a) the effectiveness of the management system and its processes;*
> *b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;*
> *c) provision of required resources;*
> *d) any need for change."*

Management review normally considers the types of information provided by:

- Managerial reports
- Quality system audits
- Performance audits (such as proficiency testing or interlaboratory comparison results)
- Client feedback
- Internal quality control measures and trends
- Trends in NCs, PNCs and complaints.

6.6 Follow up and Review of Findings

Quality system measurement and monitoring exercises such as internal audit and management review will produce findings requiring action on the part of all laboratory staff. These findings will most likely be NCs, PNCs, or OFIs. (See Chapter 5 – Continual Improvement)

Once raised and recorded within the laboratory's continual improvement program, they become corrective and preventive actions the same as for those raised from other quality system identification mechanisms. Within the continual improvement program of the laboratory, as with other corrective and preventive

actions, the implementation of these actions should be followed up after close out, to determine if they have achieved the desired results.

Follow up activities for both corrective- and preventive-actions allow a laboratory to determine that the implemented action did what was required.

Management review findings can sometimes be treated separately, depending on the top management perception of the type of findings raised during management review. If treated separately, they must still be tracked, closed out and followed up for effectiveness within the management review processes, if not the overall continual improvement program.