# MOTIVA 17025 Guide

MOTIVA Training

*Motivating Best Practice in Lab QMS*

REV 2

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# INTRODUCTION - LABORATORIES AND COMPETENCE

The standard against which laboratories are accredited (formally recognised for their competence) is ISO/IEC 17025:2005. It is entitled – *General Requirements for the Competence of Testing and Calibration Laboratories.* The standard is about one thing only – Competence of Laboratories.

"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 17025:2005 is a demonstration of competence. The demonstration of conformance 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.

ISO 9000:2005 defines quality as the "degree to which a set of inherent characteristics (of a product or process) fulfils requirements". It also defines competence as "demonstrated ability to apply knowledge and skills".

Without "judging" the competence of a laboratory, its demonstration of conformance to ISO 9000:2005 would not give anyone any confidence that the people in that laboratory know what they are doing. Anyone hired to work in the laboratory could simply follow procedures without understanding the science behind a measurement or test, and this would allow them to conform to a stated specification – but they would not necessarily be "competent."

Notes:

- ISO/IEC 17025:2005 is not a perfect document. It was created and written by imperfect people who made mistakes in creating it. It is, however, the most comprehensive and complete set of criteria that a laboratory can implement for a quality system that serves laboratory needs.
- A laboratory quality system which conforms to ISO/IEC 17025:2005 can also be part of a larger quality system which conforms to ISO 9000:2005. In other words, a company can have ONE quality system that conforms to BOTH standards.

# SECTION 1 – SCOPE OF THIS GUIDE

## Aim

To provide laboratory staff and quality system personnel with some understanding of the requirements within ISO/IEC 17025:2005 to maintain a quality system that meets these requirements.

## Topics covered

- Use and value of ISO/IEC 17025:2005
- What does ISO/IEC 17025:2005 want from you?
- Principles behind the standard
- Management requirements overview
- Technical requirements overview
- Measuring and monitoring the QMS
- Documenting competence
- Uncertainty and traceability

## Getting There from Here

The first thing to remember about a laboratory quality system is that **IT IS SUPPOSED TO WORK FOR YOU – AND NOT THE OTHER WAY AROUND**.

Laboratory quality management systems help us do our jobs better. They organise things in such a way that we can concentrate on the science at hand, the conduct of the test methods, the results produced, their interpretation and the thousand-and-one little things we can think of to get better, more precise results.

This guide is designed to highlight specific requirements of a laboratory quality system so it can be supportive of your work. It does not cover all aspects either of the standard or of a laboratory quality system.

# SECTION 2 – TERMS AND DEFINITIONS

Most of the terms used in this guide are provided from the standard ISO definitions for these terms. Such definitions are contained in other international 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 9000:2005 – *Quality Management Systems – Fundamentals and Vocabulary*

Items such as non-conformance, corrective action and preventive action are defined in ISO/IEC 17000 or ISO 9000:2005.

## 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:

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.

## Appendix:

A unique matrix - test method combination, used by the CALA program; an appendix may contain more than one analyte.

## 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 (5.2) 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 a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realization of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence (ISO/IEC Guide 43-1).

## Competence:

Demonstrated ability to apply skills and knowledge. (ISO 9000:2005, 3.1.6)

## 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.

## Conformity/Conformance:

Fulfillment of a requirement. (ISO 9000:2005)

## 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.

## Corrective Action:

Action to eliminate the cause of a detected nonconformity or other undesirable situation. (ISO 9000:2005)

## Correction:

Action to eliminate a detected nonconformity. (ISO 9000:2005)

## 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.

## Reporting Detection Limit:

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

## Nonconformity / Non conformance:

Non-fulfilment of a requirement. (ISO 9000:2005)

## Precision or Measurement Precision:

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 5725-3:1994).
- 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 9000:2005)

## Procedure:

Specified way to carry out an activity or a process. (ISO 9000:2005, 3.4.5)

- Procedures may, or may not, be documented.
- When a procedure is documented, the term "written procedure" or "documented procedure" is frequently used.
- The document that contains a procedure can be called a "procedure document".

## 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):

Document specifying the quality management system of an organization. (ISO 9000:2005, 3.7.4)

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:

Something sought, or aimed at, related to quality. (ISO 9000:2005, 3.2.5)

## Quality Policy:

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. (ISO 9000:2005, 3.2.4)

## (Quality) System:

The organised 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. (ISO 9000:2005, 3.2.1, 3.2.2, 3.2.3)

## 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.

## Resources:

Personnel, facilities, equipment, capital, knowledge, time and 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 17025:2005.

## 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:

Determination of one or more characteristics of an object of conformity assessment, according to a procedure

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., lead 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:

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.

## Verification:

Confirmation through examination of a given item and provision of objective evidence that it fulfils specified requirements. [modified from ISO 9000:2005, item 3.8.4]

Note: Verification should not be confused with calibration, or *vice versa*.

# SECTION 3 – UNDERSTANDING CONFORMITY ASSESSMENT

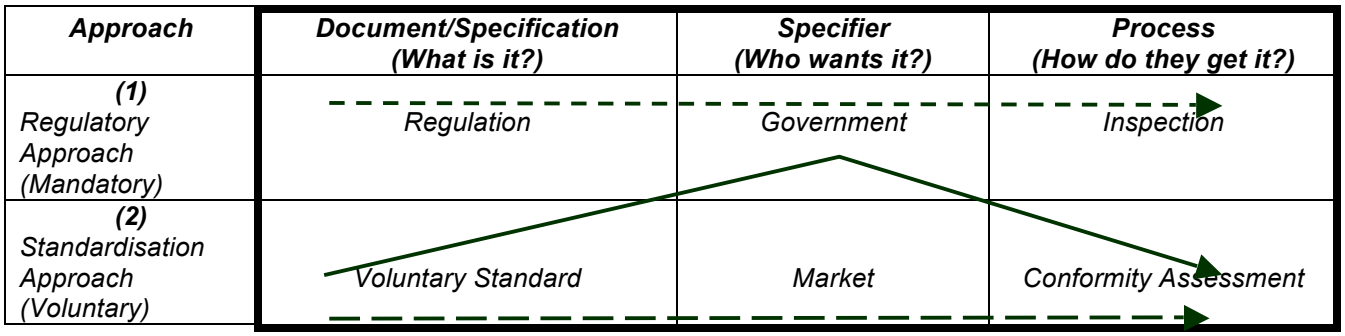
There are many ways to implement practices that help us do our jobs better in laboratories. The only difference between them is "why" the improvement is needed. If it is needed to help enforce a very stringent law, then constant inspection may be the best approach. If being able to implement demonstrable competence is what is needed, a laboratory quality system that conforms to ISO/IEC 17025:2005 may be the best approach. The approach selected depends entirely on the reason for the needed improvement.

Laboratory quality systems that conform to ISO/IEC 17025:2005 are to help the laboratory produce valid results, and show to others that it is capable of doing so. This is the concept of "competence."

Unlike a manufacturing facility, where the needs of the customer are balanced against the ability of the organisation to meet them, a laboratory has only one master – that that master is the science that underlies its test results. While a manufacturing facility can be registered to the world's best "model-for-excellence" standard (ISO 9000:2005) in order to instil stakeholder confidence in its work, a laboratory gains the trust of its stakeholders (including regulators) through demonstrated competence only.

How can regulatory agencies participate in this effort? See the chart below. It shows the differences between the two main approaches used by regulators to "protect the health, welfare and safety" of citizens within their jurisdiction.

## Standards vs Regulations




The short-dashed line at the top shows how a government develops a regulation, then specifies its use, and finally enforces it through inspection. Examples are laboratory-licensing programs used by the some jurisdictions.

The long-dashed line at the bottom is an example of how ISO/IEC 17025:2005 was delivered to drinking water laboratories in Ontario prior to Walkerton. It is also the main process used in delivering ISO 9000:2005 today. Both standards were developed from within their own community. 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 solid line in the middle represents how a government can specify a voluntary standard within its regulations. ISO/IEC 17025:2005 and relevant guidelines are delivered today to laboratories seeking to do business in a specific field by meeting 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 jurisdictions 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

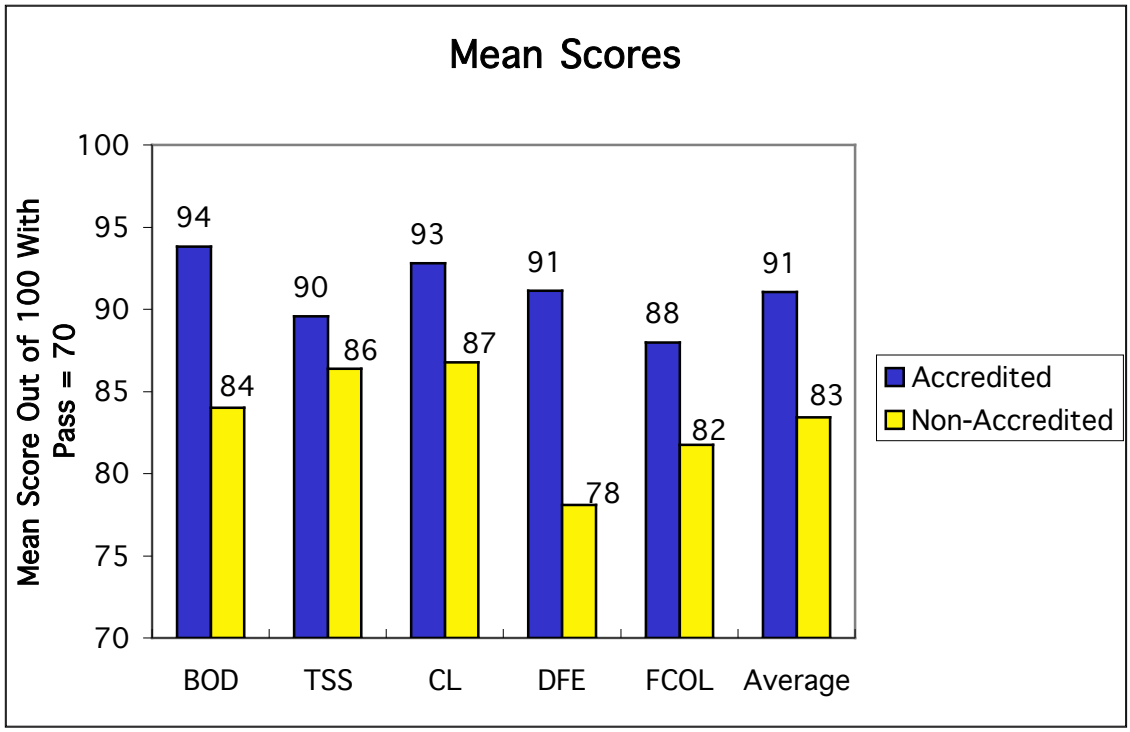
market or some legislation), and determining how to evaluate performance against the specification (inspection or conformity assessment).

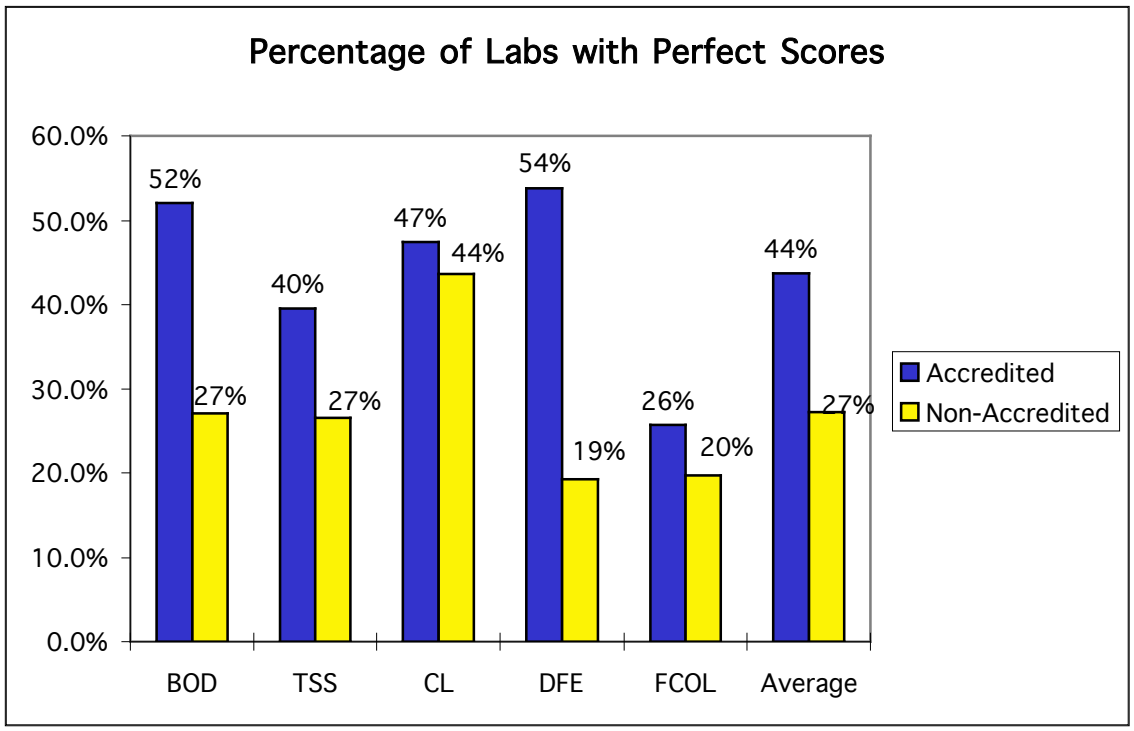
# SECTION 4 – HOW A LABORATORY QUALITY SYSTEM ADDS VALUE

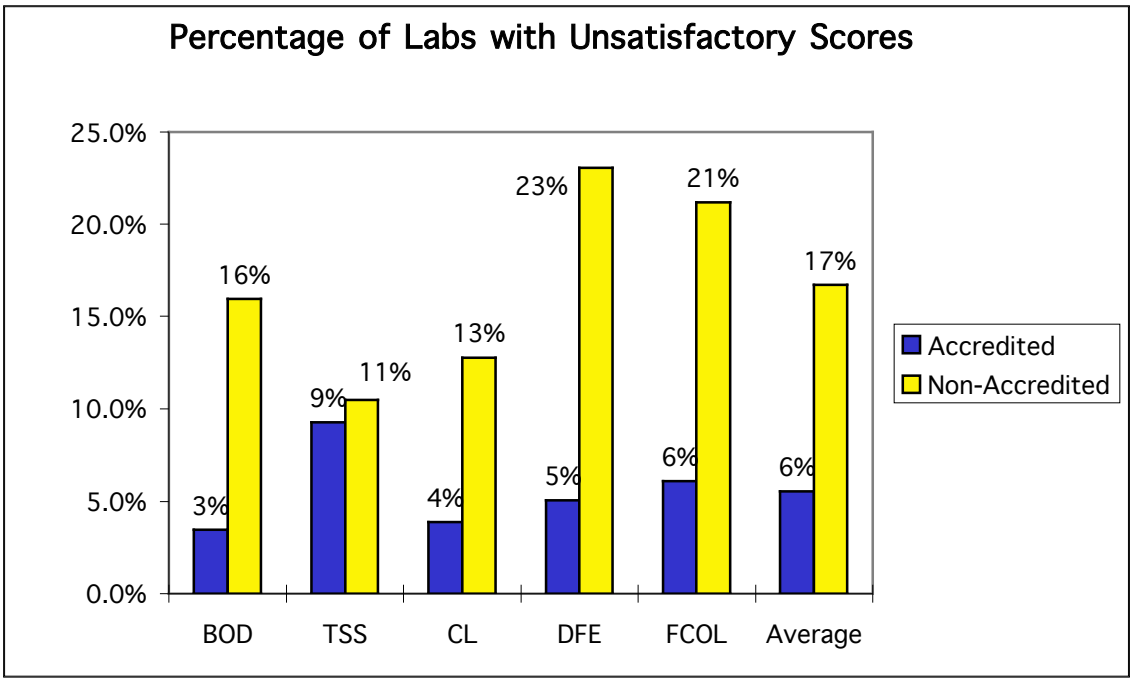
CALA has conducted a number of studies on the relative performance of accredited and non-accredited labs. The results have been published in many fora and provide clear evidence that accreditation improves overall laboratory performance.

In 1997, the proficiency testing performance of accredited laboratories from the CALA program was compared to the performance of non-accredited laboratories that received identical proficiency testing samples. A total of six proficiency testing studies were available between 1994 and 1996, and five proficiency testing parameters were chosen for this comparison: Biochemical oxygen demand (BOD), total suspended solids (TSS), Chloride (CL), Dissolved Iron (DFE), and Fecal Coliforms (FCOL). In total, 528 sets of results from accredited laboratories were compared with the same number of results from non-accredited laboratories.

Accredited laboratories achieved higher mean scores, a greater number of perfect scores, and fewer unsatisfactory scores. This pattern held for each of the five parameters as well as for the combined data set. In the illustration shown below, unsatisfactory results may be expected up to 5% of the time due to the statistical treatment of the data.






These studies have been repeated and all results are available for downloading and viewing at http://www.cala.ca/aboutus.html.

# SECTION 5 – THE PRINCIPLES BEHIND ISO/IEC 17025:2005

ISO/IEC 17025:2005 is a standard that sets out the specific requirements to be met by laboratories wishing to achieve the production of competent results as a matter of course. These requirements were developed by groups of laboratory experts from around the world over the course of 30 years. From the first, laboratory competence has been the paramount consideration.

During the course of their work, persons attempting to implement a quality system based on the standard will encounter a situation where they may question a particular requirement. While they understand the specific requirement, they may not be able to clearly articulate why such a requirement exists, in the first place. That is to say - they may not be able to identify the principles that underlie the stated requirement.

At the same time, a laboratory's blind adherence to each of the requirements of the standard, while better than no system at all, is not an approach which instils confidence in their ability to produce valid results.

Finally, ISO 9000:2005 is a well known and respected standard that aims at allowing conforming organizations to implement a "model for excellence." While some may see this aim as a very ambitious one for any organization, the standard effectively breaks down the elements that an organization can readily achieve in their implementation of such a model. One of the great strengths of ISO 9000:2005 is its clear basis on principles that can be easily articulated and understood.

Those who live and work in the world of laboratories also adhere to specific principles. These different principles provide a clearly understood basis for the requirements of the standard that most directly impacts laboratory operations.

In 2001, it was necessary to introduce the concept of having principles behind the requirements of ISO/IEC 17025:2005 and Ned Gravel produced the paper “The Principles Behind ISO/IEC 17025”. This paper was used to further discussions on the ISO/CASCO working group involved in the alignment of the standard to ISO 9000:2005. What follows is taken from that paper.

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 judgment in assessing the conformance of a laboratory to each of the requirements within the standard.

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

## Scientific Method

Concept that the work carried out by the organisation 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 organisation, 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 that 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.

# SECTION 6 – OVERVIEW OF MANAGEMENT REQUIREMENTS

*(Numbers shown are the clause numbers taken from ISO/IEC 17025:2005)*

## Clause Requirement

### 4.1 Organisation and Management

4.1.1 Legal identification of the laboratory and its organisation.

4.1.2 Includes stipulation to meet regulatory requirements.

4.1.3 Allows “mobile” and “temporary” facilities to be covered by the requirements of the standard.

4.1.4 IDENTIFY and DOCUMENT potential conflicts of interest and how to deal with these.

4.1.5 Additional documentation is required for quality system sections dealing with:

b (undue pressure),
c (client confidentiality) **[explicitly],**
d (avoid activities that diminish confidence) **[explicitly],**
e (defining organisational structure), and
f (responsibility for testing, QA, management)

4.1.6 Top management is to ensure appropriate communication within the organisation so that the quality management system system can be implemented and maintained.

### 4.2 *(Quality)* Management System

4.2.2 Laboratory Quality Policy statement must have all of the parts of a) through e) in it.

4.2.3 Top management commitment to: developing and implementing a quality management system, and continual improvement.

4.2.4 Top management to communicate importance of meeting customer and regulatory requirements.

4.2.5 IDENTIFY and point to supporting procedures. Methods are treated separately.

4.2.6 Roles and responsibilities of:

- Technical management
- Quality management

4.2.7 Top management to ensure integrity of quality management system in the face of changes.

### 4.3 Document Control

4.3.1 Defines documents to be controlled. Laboratory must show how they update external docs, standards, etc.

4.3.2 Document approval and issue procedures, including a MASTER LIST.

4.3.3 Changes to documentation. (Approval of amendments - even the handwritten ones).

## 4.4 Review of Requests, Tenders and Contracts

4.4.1 Is the laboratory capable? Labs must follow this process. See the principle of "Capacity."

4.4.2 Records of review, changes etc.

4.4.3 Includes work subcontracted by the laboratory to another.

4.4.4 Inform the (client) customer of any deviation from contract.

4.4.5 Conduct the same review process before any amendment to the contract

## 4.5 Subcontracting of tests and calibrations

(*everything on a scope of accreditation*)

4.5.1 Use only competent subcontractor (how do you define competent?)

4.5.2 (Client) Customer advised, preferably in writing.

4.5.3 Lab is responsible to the (client) customer for all work, including subcontracted work. The subcontractor is not responsible to the (client) customer, only to the lab (you). The lab (you) is(are) responsible to the (client) customer.

4.5.4 Checking the competence of the subcontracted lab. Register of subcontractors and evidence of conformance to ISO/IEC 17025:2005

## 4.6 Purchasing Services and Supplies

(*everything not on a scope of accreditation*)

4.6.1 For all services and supplies that affect the quality of test and/or calibration results. (Pencils? No.----- Calibration services? Yes)

4.6.2 "Ensure purchased supplies …verified as complying with standard specifications….." Are the calibration service providers competent to provide this service? How can a laboratory verify this?

4.6.3 Approval by "technical staff" of services and supplies to be purchased. Records of how the technical staff reviewed and approved.

4.6.4 Evaluation of suppliers (not supplies) of critical consumables, supplies, and services. Documented. (Define critical??)

## 4.7 Service to the *(Client)* Customer

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4.7.1 Cooperating with (client) customer.

- "Reasonable" access but maintain confidentiality
- Seek *(client)* customer feedback
- Documented approach and procedures
- Same as 4.19 of ISO 9000:1994 and in accordance with the principle of "Customer Focus" in ISO 9000:2005

4.7.2 Acquire (client) customer feedback – both positive and negative. See "complaint" below.

## 4.8 Complaints

Laboratory must have records of the treatment of complaints

## 4.9 Control of nonconforming testing and/or calibration work

(*See section on Continual Improvement in this guide*)

4.9.1a. Stated policies and procedures on what happens when any nonconformance is found. Then for implementation

4.9.1b. The lab's documented evaluation of the significance [and impact] of the nonconformance.

4.9.1e. Documentation detailing the responsibility of resumption of work whenever nonconformance results in stopping work.

4.9.2. When nonconformances are discovered and questions regarding the conformance of the quality management system arise, corrective action shall be taken.

## 4.10 Improvement

(*See section on Continual Improvement in this guide*)

This clause requires the laboratory to identify opportunities for improvement – and then to act on them.

## 4.11 Corrective Action

(*See section on Continual Improvement in this guide*)

This clause is a follow on from 4.9 (Nonconformances). 4.11 is identification of problem "after" the fact. This is a different from the one 4.12 - Preventative Action, which is identification of problem "before" the fact.

4.11.2 Documented analysis of root causes of non-conformances

4.11.3 Reasoned [and documented] selection of the most appropriate corrective action and its documented implementation

4.11.4 Monitor the results of the corrective action. Documented.

4.11.5 Conduct additional audits, if required, to ensure that the quality management system is operating effectively.

## 4.12 Preventive Action

(*See section on Continual Improvement in this guide*)

4.12.1. Documented policies and procedures. Actions plans developed, then implemented, then monitored - all aimed at "continual improvement." The laboratory should actively seek to "identify opportunities for improvement." Use Management Review minutes, client feedback from 4.7, quality committee minutes, etc:

- Identify "needed" improvements
- Identify "potential" non conformances

4.12.2 Initiate preventive actions and ensure they are effective.

## 4.13 Control of Records

- Includes all records, technical and non-technical

- Includes all of the documentation, paper and electronic.
- Requirements
  + Legible,
  + readily retrievable,
  + suitably stored.

4.13.2 (Technical records) From the generation of any data, including receipt of samples, through to issuance of report. ALL technical records generated within the scope of accreditation.

Records provide sufficient information for two things: traceability for all actions from receipt of sample to report, and documented exercise of responsibility for all involved in the process.

## 4.14 Internal Audits (*See section on Measuring and Monitoring the QMS in this guide*)

- To audit ALL laboratory activities
- ILAC and APLAC say “one year”. See APLAC TC 002.

4.14.4 Also used to verify the implementation of corrective actions.

## 4.15 Management Review *(See section on Measuring and Monitoring the QMS in this guide)*

ILAC and APLAC say “one year”. See APLAC TC 003

4.15.1 ALL of the (applicable) elements given in this paragraph must appear in the minutes of a management review meeting.

# SECTION 7 – OVERVIEW OF TECHNICAL REQUIREMENTS

## Clause Requirement

### 5.2 Personnel

5.2.1 Competence and training. Is it documented? Are personnel supervised?

5.2.2 Training goals. Is it documented? Effectiveness of training actions to be evaluated.

5.2.3 Competence of contracted personnel? Supervised? Documented qualifications?

5.2.4 Job descriptions. Dated and preferably signed by the incumbent.

5.2.4 How does the laboratory document its selection of persons to do the following?

- 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
- Evidence of competence

5.2.5 Formal qualification for all personnel. Documented.

### 5.3 Accommodation and Environment

5.3.1 Adequate for testing? Also for off site sampling and testing.

5.3.2 Environmental control. Recorded. Monitored according to specifications for testing.

5.3.3 Separation to prevent cross-contamination

5.3.4 Control of access. Authorised persons only

5.3.5 Good housekeeping. Safety. See Clause 1.5

### 5.4 Methods and Method Validation

5.4.1 Documented methods for all aspects of lab operations

5.4.2 Considered selection of the methods to be used

5.4.3 and 5.4.4 In-house methods and non-standard (non-routine) methods must meet the same requirements as externally derived standard methods.

5.4.5 Definition of method validation: "…confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use [of the Method] are fulfilled."

5.4.5.2 "The laboratory shall validate…" "The validation shall be as extensive as necessary to meet the needs of the given application or field of application..."

5.4.5.3 All method parameters determined during validation need to be "fit for purpose."

5.4.6 Estimate the uncertainties associated with calibrations and tests. It is important to note that estimating uncertainties is best dealt with during the validation of the method. The two exercises create and use the same data.

Exercise appropriate control of the data generated by calibration and testing activities.

- Document and validate software used to acquire and/or manipulate data
- Protect the data
- Keep it confidential
- Maintain the integrity of the data.

## 5.5 Equipment

5.5.1 Laboratory has all required equipment in house. If not, the externally supplied equipment falls under the control of the laboratory when it is used by the laboratory. Who is responsible for the maintenance of this equipment?

5.5.2 Equipment is "fit for purpose." Capable of desired accuracy? Documented? Checked for fitness prior to use?

5.5.3 Operated only by authorised persons

5.5.4 Uniquely identified

5.5.5 Equipment records. Includes calibration certificates.

5.5.6 Safe handling and transport. Procedures?

5.5.7 Defective or suspect equipment. (Now what?)

5.5.8 Visible calibration status

5.5.9 Equipment that is returned to the laboratory is re-checked for fitness prior to use. Documented procedures?

5.5.10 Written procedures for checks and verifications

5.5.11 Effects of calibrations made available to all personnel required. Correction factors? Stored where? Updated?

5.5.12 All equipment protected from unauthorised or inadvertent adjustment.

## 5.6 Measurement Traceability

(*See section on Uncertainty and Traceability in this guide*)

All measuring equipment used in the lab must be traceable to the SI through a National Metrology Institute (NMI) via an unbroken chain of comparisons. (First problem)

All measurements produced by the lab include the uncertainty of that measurement. (Second problem)

"Calibration", "Traceability", "Uncertainty" are all required for ANY of these to EXIST. None of these are deemed to be present unless ALL are present.

Requirement for Traceability

- Uncertainty of any measurement is required in order to establish the confidence that an interpreter of results can have in that measurement.
- Traceability of the measurement is required to estimate the uncertainties associated with it.

- At the same time, uncertainties established along the traceability chain are the basis for the establishment of traceability of the measurement

Uncertainty Contributions

- Type A - estimation based on repeated independent measurements (Statistical)
- Type B - estimation based on the physical set-up of the test and other empirical data.

Formal Science in international publications that govern.

- "Guide to the Uncertainty of Measurement" (GUM) published by ISO, IEC, CIPM, BIPM, Eurachem etc.
- Vocabulaire internationale de metrologie (VIM)

Use of Statistics. Both the VIM and the GUM detail the methods of statistical estimation of uncertainties associated with measurements.

5.6.2.1 This is for calibration laboratories. This is the crux of all calibration laboratory work.

5.6.2.2 This is for testing laboratories. Follow the same approach used in 5.6.2.1 - except the rigour required for conducting calibrations may be less for testing laboratories - because the uncertainties required may be significantly larger (not true in all cases)

5.6.3.1 and 5.6.3.2.
Reference standards and reference materials need to provide traceability as well. (Is the laboratory that provides the Certificate of Analysis accompanying the Reference Standard accredited for that test?)

5.6.3.3 and 5.6.3.4
Monitor the performance of reference standards and materials.
Ensure transportation and storage does not adversely affect the required performance of reference standards and materials.

## 5.7 Sampling

- The laboratory does its own sampling (easy)
- The laboratory accepts samples from others (hard)
- Procedures for sampling given to the sampling agency before sampling takes place
- Sampling procedure followed and documented by the sampling agency.
- The laboratory records all relevant sample information
- Affects of sampling are carried forward to the result produced, where this is applicable.

## 5.8 Handling of Test and Calibration Items

- Laboratory has procedures
- Laboratory tracks the samples from receipt to disposal
- Each sample uniquely identified
- Each sample examined on receipt for "fitness for purpose"
- Protection, storage, handling, and disposal of samples. (who owns the sample when testing is completed?)

## 5.9 Assuring the quality of test and calibration results

5.9.1 This clause provides a good listing of useful methods for laboratory QC.

- Best tool for laboratory QA is a good PT/ILC program. But it must be monitored to be effective.
- There are other good QA/QC practices?

5.9.2. Quality control data to be analyzed (such as control charts, etc). Planned action (see 4.11 and 4.12 above) is to be taken to correct/prevent problems and to prevent incorrect results from being reported.

## 5.10 Reporting the Results

5.10.1 Test Reports and Calibration Certificates are the PRODUCTS of accredited laboratories - regardless of the client.

5.10.2 Basic requirements of these products.

5.10.3 Specific requirements of test lab reports.

5.10.3.1c) Testing laboratories must be prepared to report uncertainty

- "when relevant to the validity of the test results"
- "when requested by the client"
- "when uncertainty affects compliance to a specification"

(*See section on Traceability and Uncertainty in this guide*)

- *Laboratories must estimate and report uncertainty for all test results produced.*
- *Identify and estimate all components of uncertainty*
- *Account for all important uncertainty contributions*

5.10.4 This section gives a good idea of what the standard calls upon calibration labs to do….and should deliver to test labs.

*Uncertainty is the only real result of a calibration.*

**NO UNCERTAINTY**
**= NO CALIBRATION**
**= NO TRACEABILITY**

5.10.5 Specific requirements for providing the added value of an interpretation or an opinion - based on the result.

Lab must have competent persons designated for this activity - assessed separately from the lab ability to produce competent results. (Results are Objective - Opinions are Subjective)

5.10.6 Identify all results not produced by the laboratory issuing the report/certificate.

5.10.7 Treat electronic acquisition, storage, manipulation, and transmission of results the same as for paper copies

5.10.8 Format reports to be "fit for purpose"

5.10.9 Amendments only allowed in the issuance of a "supplementary report" that is clearly identified as such.

# SECTION 8 – CONTINUAL IMPROVEMENT IN A LABORATORY

## Start with Non conformances and potential non conformances.

ISO 9000:2005 defines "*non-conformity*" as "*non-fulfilment of requirement*."

The non-fulfilment of specified requirements can be:

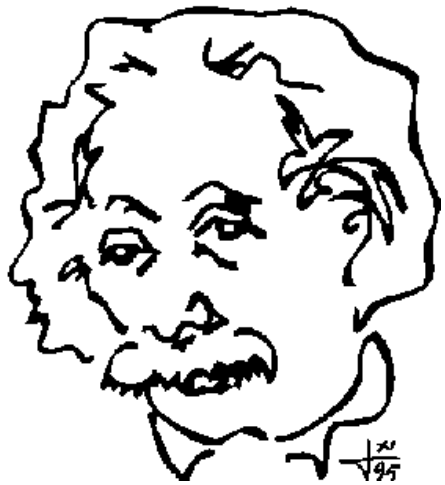
1. failure of resources to meet either performance requirements or other specified requirements
2. failure of organisation to comply with documented policies and procedures or work instructions
3. failure of test data to meet required standards; i.e.
    - failure to meet all conditions necessary to 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).

## The Purpose of Continual Improvement

ISO 9000:2005 states that the aim of continual improvement of a quality management system is to increase the probability of enhancing the satisfaction of customers and other interested parties. Actions for improvement include the following:

- analysing and evaluating the existing situation to identify areas for improvement;
- establishing the objectives for improvement;
- searching for possible solutions to achieve the objectives;
- evaluating these solutions and making a selection;
- implementing the selected solution;
- measuring, verifying, analysing and evaluating results of the implementation to determine that the objectives have been met;
- formalizing changes.

Results are reviewed, as necessary, to determine further opportunities for improvement. In this way, improvement is a continual activity. Feedback from customers and other interested parties, audits and review of the quality management system can also be used to identify opportunities for improvement.



If perfection in a testing laboratory were to be described, and perfection was based on the principles behind ISO/IEC 17025:2005, 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? Is there some state of perfection that is the objective for continual improvement?

ISO/IEC 17025:2005 is about only one thing – laboratory competence. Laboratories that have implemented a quality system that conforms to ISO/IEC 17025:2005 should be able to produce valid results…but to what degree, or level?

The authors of ISO/IEC 17025:2005 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 17025:2005 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 organisation 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."***

# How to Implement Continual Improvement in a Laboratory

ISO 9001:2000 describes the process of continual improvement as having the following steps:

- identifying non-conformities and potential non-conformities
- determining the need to prevent occurrence of potential non-conformities or recurrence of non-conformities
- determining the causes of non-conformities
- 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"* below. They are nearly identical. This is once instance where the concept presented in ISO

9000:2005 provides a better model for laboratories to follow, than simple interpretation of the wording in ISO/IEC 17025:2005 clauses 4.9, 4.10, 4.11, and 4.12.

The list shown at the bottom of the bubble diagram is even better at visualising the processes involved.

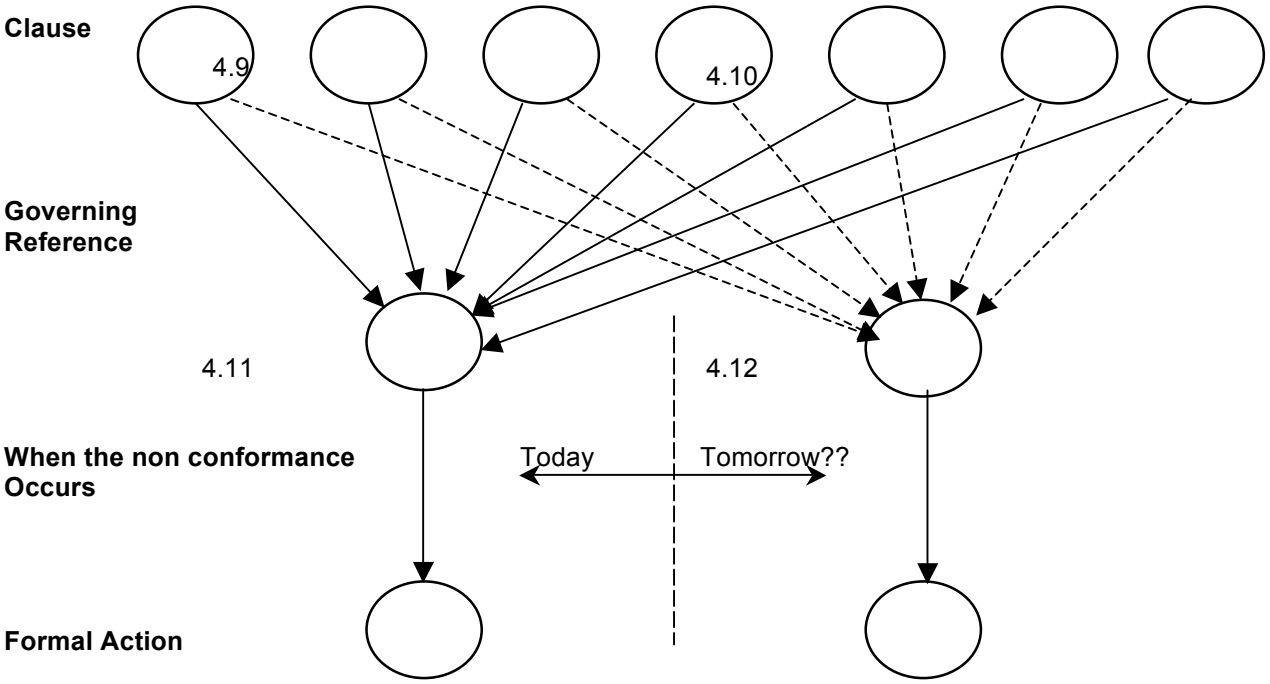
The laboratory can now formally document its continual improvement goals, processes, procedures and forms by simply pointing to its own efforts in corrective and preventive action.

ISO/IEC 17025:2005 contains seven (7) clauses that facilitate our ability to find these “non-conformities.” They are:

4.7 – Service to the client
4.8 – Complaints
4.9 – Control of Non-Conforming Work
4.10 – Improvement
4.14 – Internal Audits
4.15 – Management Review
5.9 – Quality Control.

All of these clauses provide some direction on the search for non-conformities. Because ISO/IEC 17025:2005 is not a perfect document, it neglects to specify that these same clauses can also be used to search for “potential non-conformities” as well. In fact, it dedicates an entire clause on what to do when a non-conformance is discovered (identified). It now gives some indication on what to do when a “potential non-conformance” is discovered.

# From Identification to Action




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

# Corrective and Preventive Action

ISO/IEC 17025 is focussed on a laboratory's ability to produce valid results, and non-conformities 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 non-conformities – today and tomorrow.

If we understand that potential non-conformances are only the identification of a POTENTIAL or POSSIBLE non-fulfilment of specified requirements, then it becomes much easier to determine the best course of action in their treatment.

What can be done to address both non-conformances and opportunities for improvement/potential non-conformance?

- Understand that a non-conformance is different from a potential non-conformance in only one aspect - Time. The latter has not yet resulted in a non-conformance while the former has already occurred.
- Understand that non-conformances can be dealt with by simply correcting an aberrant condition or undertaking the more formal process of corrective action – more about this later.
- Understand that potential non-conformances 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.
- Understand that the laboratory quality system needs to address both of these sets of circumstances.

## What does this mean to the lab?

- The processes for capturing both identified non-conformances and potential non-conformances can be the same…same procedures, same forms, and same approach. The only stipulated difference is Time.
- The processes for addressing both identified non-conformances (corrective action) and potential non-conformances (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 potential non-conformances. They understand them better and they more certain about which is which.
- Implementing this approach in a formal manner also allows the laboratory to pro-actively implement continual improvement.

## The Need for Corrective or Preventive Action

Whenever non-conformances, potential non conformances or opportunities for improvement 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 as described in Lesson 1 of this course. See Section 1.4.5.2 – *From Identification to Action*.

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:

1. Does this condition adversely affect my demonstrated competence, such as producing and delivering an invalid result, or potentially doing so?

2. Does this condition create unacceptable risk to the organisation? This can be most simply derived by estimating the costs associated with the non-conforming condition, whether it has already occurred or may occur (potential non-conformance) and multiplying that number by its probability of occurrence.

   ***RI$K = IMPACT of NON-CONFORMANCE X PROBABILITY***

3. Does full corrective- or preventive-action cost less to implement than simple (and repeated) correction/prevention?

If any of these questions result in a “Yes”, full corrective- or preventive-action is needed, starting with an analysis for root cause. If ALL of these questions result in a “No”, no root cause analysis is needed and and simple correction / prevention (even if repeated) is acceptable.

# 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.

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.

# 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 choice of potential solutions is impersonal and may be developed independent of others.

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.

## 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.

## Monitoring Solutions, Follow up and Timelines

Clause 4.11.4 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. Clause 4.11.5 then requires additional audits whenever a non-conformance casts doubt on the laboratory's conformance to requirements. Follow up activities allow a laboratory to determine that the implemented action did what was required.

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. See the last box on the sample ICAR.

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.

***In other words:*** *Does the quality system adequately support the laboratory's ability to produce valid results, and is it allowing for continual improvement?*

# SECTION 9 – MEASURING AND MONITORING THE QUALITY SYSTEM

When an organisation 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 valid results. The second aim of an internal audit is to determine if there are adequate opportunities for continual improvement.

An internal audit is the best tool an organisation 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 organisation.

ISO/IEC 17025:2005 separates these measurement and monitoring functions into two clauses, 4.14 – *Internal Audits* and 4.15 – *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 organisation to produce valid results and concentrates on the requirements of the standard. An internal audit concentrates on the requirements given in the organisation's own quality system documentation.

## 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.

## Internal Audit

The definitions for “audit” are given above 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 “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 good information to the people that work in the laboratory and its top management on where effort may be required to improve the system. It allows top management to do their job.

Top management:

- Are the owners of this process,
- Sell the requirement to the staff,
- Approve the internal audit program and plan,
- Facilitate implementation of the requirement (remove obstacles for its accomplishment),
- Provide 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 organisation that seeks to have detailed knowledge about how well it is doing its own business is headed in the right direction. Such an organisation is well led and not afraid to ask itself the hard questions.

In good organisations, 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 / opportunity for improvement challenges are encountered.
- Implement corrective action solutions when approved.
- Maintain the quality system as specified.
- Actively seek out opportunities for improvement.
- 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. Recognise 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 non-conformances. 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

## Management Review

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:

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

**Section 4.15 of ISO/IEC 17025:2005 states:**

> “In accordance with a predetermined schedule and procedure, the laboratory's executive management shall periodically conduct a review of the laboratory's quality system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:
>
> - the suitability of policies and procedures;
> - reports from managerial and supervisory personnel;
> - the outcome of recent internal audits;
> - corrective and preventive actions;
> - assessments by external bodies;
> - the results of interlaboratory comparisons or proficiency tests;
> - changes in the volume and type of the work;

- client feedback;
- recommendations for improvement;
- complaints;
- other relevant factors, such as quality control activities, resources and staff training.

NOTE 1 A typical period for conducting a management review is once every 12 months.
NOTE 2 Results should feed into the laboratory planning system and should include the goals, objectives and action plans for the coming year.
NOTE 3 A management review includes consideration of related subjects at regular management meetings."

Management review normally considers the types of information provided by:

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

# SECTION 10 – IT IN THE LABORATORY

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

## General Guidelines

General guidance on acceptable and appropriate methods for making use of IT in support of testing can be found in *MOTIVA Guidance on the use of Computers in Accredited Laboratories*. 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

## 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. [4.3, 4.13]

- 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.

## 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 5.4.7.2 of ISO/IEC 17025:2005, 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 5.5.2 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. [5.4, 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
- 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."*

## 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. [4.3, 4.13, 5.4, 5.5]

- 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.

## 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. [4.3, 4.13]

- 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

## 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 effect the maintenance of electronic systems (software and applications), which may include software, firmware and/or hardware, so as to prevent non-conforming operation of the electronic system. [5.5]

- Operation by trained and qualified personnel
- Preventive maintenance schedules for hardware.
- 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
- 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.

# Clause-by-clause Citations

The clauses in ISO/IEC 17025:2005 that apply in the use of electronic systems support for laboratories are given below:

| Clause | Extract / Wording | Policy Consideration |
|---|---|---|
| 4.1.5.c | "…shall have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results..." | **Integrity of data and Access control** Procedures exist to protect client's information |
| 4.3.1 | "…shall establish and maintain procedures to control all documents…. ….. in this context, "document" could be … …. software…. These may be on various media, whether hard copy or electronic, ….." | **Integrity of data and Access control** Procedures to control software |
| 4.3.2.1 | "All documents issued… ….shall be… …reviewed and approved for use…." | **Integrity of data** Quality system reviewed and approved by authorized personnel by electronic signatures or password protection and/or retention of approval records in hard copy. |
| 4.3.2.2 | "The procedure(s) adopted shall ensure that:<br>a) authorized editions of appropriate documents are available at all locations….." | **Integrity of data and Retrieval of data** Authorized editions of appropriate documents all locations. (Intranet, NT file Share) |
| 4.3.3.2 | "..the altered or new text shall be identified…" | **Integrity of data** Altered or new text shall be identified (electronic document) |
| 4.3.3.4 | "Procedures shall be established….. …documents maintained in computerized systems are made and controlled". | **Integrity of data** Procedures shall describe how changes in documents, including software are controlled. |
| 4.13.1.2 | "All records… …shall be… …readily retrievable…"<br>"…hard copy or electronic media…" | **Retrieval of data** Records (electronic media) shall be stored and maintained so that they are retrievable |
| 4.13.1.4 | "The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records." | **Integrity of data and Access control** Procedures to protect and back-up electronic records. |
| 4.13.2.1 | "…shall retain records… …to establish an audit trail…" | **Integrity of data and Retrieval of data** Retain records for the retention period (old versions of software also) |
| 4.13.2.2 | "Observations, data and calculations shall be recorded…" | **Integrity of data** Observations shall be recorded at the time they are made. (electronic). |
| 4.13.2.3 | "When mistakes occur in records,…….In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data". | **Integrity of data and Access control** Electronic records shall avoid loss to original data (audit trails)<br>Do Databases and spreadsheets include "audit trails" to not allow previously recorded data to be obscured? |

| Clause | Extract / Wording | Policy Consideration |
|---|---|---|
| 5.2.1 | "The laboratory management shall ensure the competence of all who operate specific….." | **Validation and Maintenance of electronic system**<br>Does evidence show that personnel involved in use of Custom Software have adequate training? If the Custom Software was developed in-house, is there evidence that they have adequate training in the development of these types of solutions? |
| 5.3.4 | Access to and use of areas affecting… …quality… …shall be controlled. | **Integrity of data and Access control**<br>Server rooms or server access should have limited access |
| 5.4.1 | "The laboratory shall have instructions on the use and operation of equipment…." | **Integrity of data Validation and Maintenance of electronic system**<br>This includes software.<br>Do adequate instructions exist for the operation & maintenance of the software? |
| 5.4.7.1 | "Calculations and data transfers shall be subject to appropriate checks in a systematic manner." | **Integrity of data and Validation of Electronic system**<br>Calculations (spreadsheet) and data transfers (tables) shall be subject to checks. Where other programming approaches are used to effect data manipulation and transfer, there must be some method established to ensure that these are checked as well. |
| 5.4.7.2 a) | "computer software developed by the user is documented in sufficient detail and suitably validated ….." | **Validation of Electronic system**<br>Software shall be validated and documented – even if commercial software is configured for specific use |
| 5.4.7.2 b) | "procedures are established for protecting data, such procedures shall include integrity, confidentiality…" | **Integrity of data and Access control**<br>Procedures are established to protect data |
| 5.4.7.2 c) | "computers and automated equipment are maintained…" | **Integrity of data and Maintenance of Electronic system**<br>Computer and automated equipment are maintained |
| 5.4.7.2 Note | "Commercial off-the-shelf software… …in general use, *within their design application* range, may be considered suitably validated. However, software configuration/ modifications should be validated as in 5.4.7.2 a)" | **Validation of Electronic system**<br>The software validation note allows labs to take credit for assumed validation efforts made by the manufacturer of purchased software but requires that individual spreadsheets, macros, and all configuration / modifications / setups be validated. This does not apply to electronic systems used to acquire, manipulate or reduce data, such as hard-coded *firmware*[◦] that is often supplied with computer-driven devices. |

[◦] Firmware is programming that is inserted into programmable read-only memory (programmable ROM), thus becoming a permanent part of a computing device. Firmware is created and tested like software (using microcode simulation). When ready, it can be distributed like other software and, using a special user interface, installed in the programmable read-only memory by the user. Firmware is sometimes distributed for printers, modems, and other devices controlled by computers.

| Clause | Extract / Wording | Policy Consideration |
|---|---|---|
| 5.5.2 | "Equipment, and its software…….shall be capable of achieving the accuracy required……. Before being placed in service, equipment (software) shall be calibrated or checked to establish that it meets the labs requirements·……." | **Validation and Maintenance of Electronic system**<br>Does the accuracy of the Firmware/Software meet or exceed the accuracy required by the test method or other relevant specification? A good test is the uncertainty contribution of the device (and its programming) to the overall uncertainty of the test result.<br>All deployed software should be verified prior to being placed in service by performing some user acceptance testing such as a comparison of the requirements against features. This includes placement into service following a move or after being shipped back from calibration or maintenance. |
| 5.5.4 | "Each item of equipment and its software used for testing… …shall… …be uniquely identified." | **Maintenance of Electronic system**<br>Each item of equipment & software shall be uniquely identified. Procedures should include documenting the versions in use (version control) |
| 5.5.5 | "Records shall be maintained…" | **Maintenance of Electronic system**<br>Records shall be maintained of equipment & software. |
| 5.5.11 | "Where calibrations give rise to… …correction factors… …procedures to ensure that copies (e.g. in computer software) are correctly updated." | **Validation of Electronic system**<br>Does evidence exist confirming correct software deployment at each target installation? Consider the same approach to software as for other documents such as document control (software management), distribution control. |
| 5.5.12 | Test and Calibration equipment, including software, shall be safeguarded from adjustments…" | **Integrity of data and Maintenance of Electronic system**<br>Software shall be safeguarded from adjustments such as password protection on spreadsheets or other files. |
| 5.10.1 NOTE 2 | "The test reports or calibration certificates may be… ….by electronic data transfer…" | **Integrity of data**<br>Reports may be issued electronically |
| 5.10.2.j | "the… …identification of person(s) authorizing the test report or calibration certificate." | **Integrity of data**<br>Reports may contain electronic signatures. LIMS systems should have established authorization protocols. |
| 5.10.7 | "in the case of transmission of test or calibration results by… …electronic… …means, the requirements of this International Standard shall be met…" | **Integrity of data**<br>Reports may be transmitted electronically. Whatever method of transmission is used, it must provide an the same level of protection of integrity of information afforded to paper documentation. |

# SECTION 11 – DOCUMENTING LABORATORY COMPETENCE

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

Moreover, they are all aimed at producing valid test and measurement results.

All of the things in this list can only be demonstrated through documentation and 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 17025:2005. This is the single biggest reason why ISO/IEC 17025:2005 is so prescriptive, compared to ISO 9000. Everything must be documented, including traceable records.

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. These should remain confidential between the person and the laboratory or its parent organisation. Others are very important in the laboratory's demonstration of competence. The trick is to determine which is which.

Clause 5.2.4 of ISO/IEC 17025:2005 lists some of the requirements for documenting personnel competence. In essence, how does the laboratory document its selection of persons to do the following?

- 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 organisation 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.

**Red File: (NO!!!)** ✗

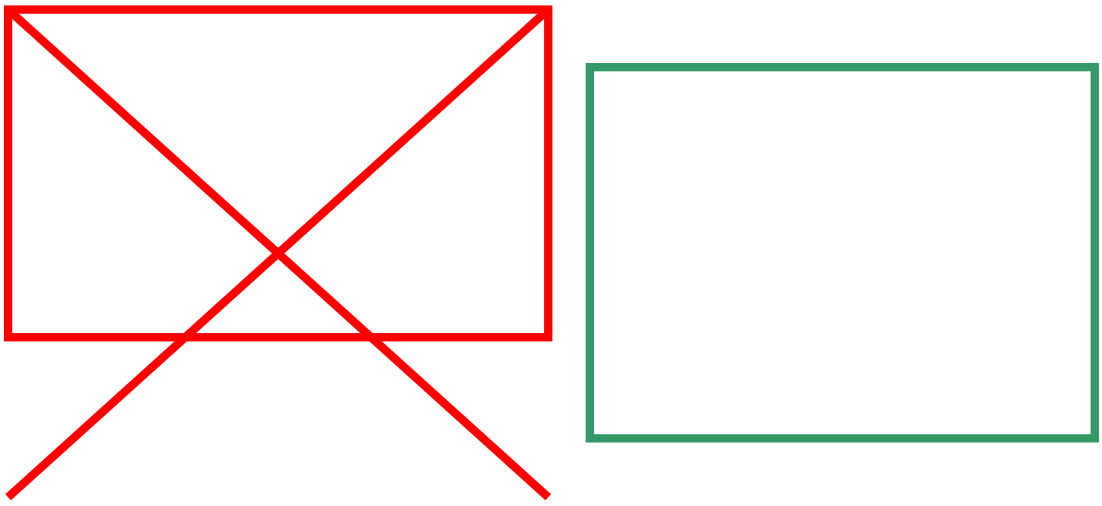
Staff performance review ✗
Pay ✗
Health issues ✗
Collective agreement issues ✗
Disciplinary issues ✗
Health Plan information ✗

**Green File: (YES)** ✓

Resume ✓
Job description ✓
Training records ✓
Qualification records ✓
Measurement proficiency ✓
Conflict of interest form ✓
Confidentiality form ✓

Consider, for example, a personnel file kept in a central file system of a large organisation. 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. Conversely, an assessor is required to review the contents of the green file. The same approach should apply to internal audits within the organisation.

Note how the contents of the green file provide information to answer the questions posed in Clause 5.2 of ISO/IEC 17025:2005.

# SECTION 12 – UNCERTAINTY

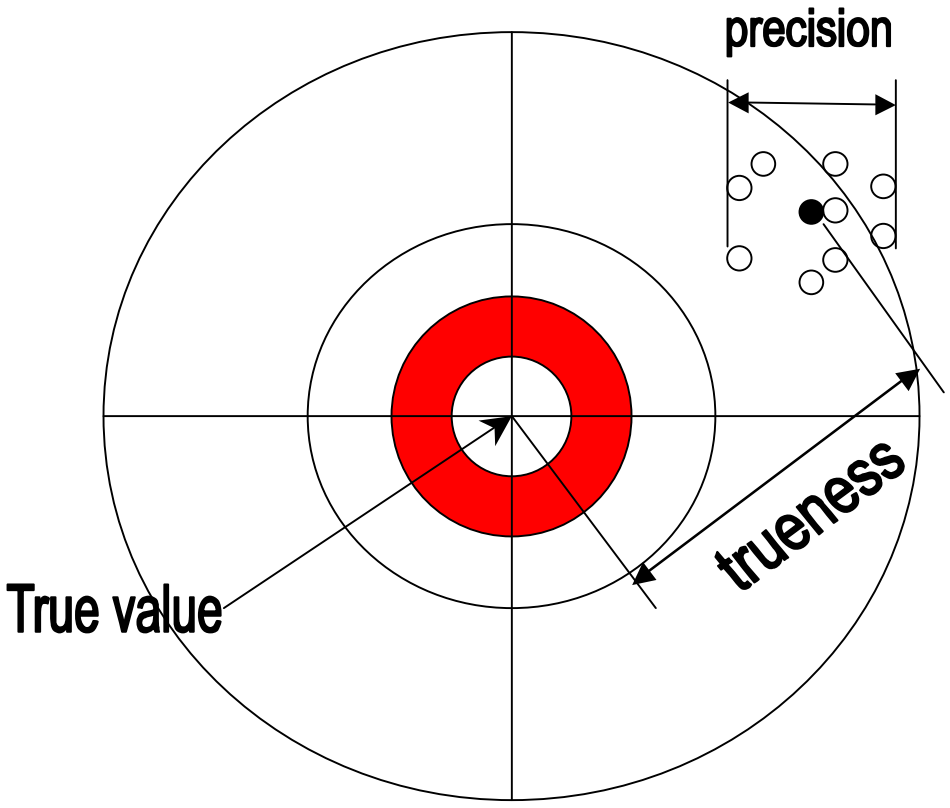
Users of laboratory data are:

- clients of laboratories who use the data,
- public sector regulatory agencies who interpret the data, and
- public sector regulatory agencies who develop policies based on data.

All users of laboratory data are faced with the concept of measurement uncertainty when receiving or examining laboratory data. It is important that users develop some understanding about the context and use of the uncertainties associated with laboratory data.

## Basic Concepts

Consider this 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.

Whether a laboratory reports a single result or the mean (average) of a set of results, the considerations for reporting uncertainty **are the same in all cases.**

### Accuracy

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

“Trueness” is how far the group of white dots is from the true value. Think of it as the distance from the true value to the black dot (mean).

### Precision

“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?

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

### Objective Quantity versus Subjective Quality

No single measurement can be given a value of accuracy. Accuracy is a subjective (qualitative) consideration. Measurements can only be assigned quantifiable estimations of precision and trueness.

The distance from the black dot to the centre of the target is 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 known as “bias”.

Appreciating these basic concepts, the important considerations can be summarised in the following question:

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

This is the **ONLY** question that measurement uncertainty answers. But it is a very important question and it generates a very important answer.

## Uncertainty Causes and Effects

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

From the previous diagram, and without giving too much away, 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.

ISO/IEC 17025:2005 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 testing laboratory results.

Calibration laboratory capability is already measured primarily by the size of the confidence region it can generate when conducting calibrations. Uncertainty is the business of a calibration laboratory.

## Uncertainty is a Regulator’s Measure of Laboratory Quality

Regarding the requirement to report when the uncertainty affects compliance to a specification limit, the laboratory may not have been given the information to make a decision regarding compliance, but the Province of Ontario has made it a crime for a laboratory to not report exceedence of the compliance limits for drinking water. Accredited laboratories that test drinking water in Ontario know the specification limits.

Within the duty of care, laboratories are expected to ensure traceability of measurement and to establish that the samples and the resulting data are “fit-for-purpose.” Traceability applies directly to the “trueness” of the measurement result and the sample and data fitness apply directly to the “precision” of the measurement – or its uncertainty. Any person or organisation with a stake in the reported result can read the associated uncertainties and make a determination of the quality of the result.

Within the duty to warn, laboratories need to tell clients and, if applicable, regulators when a specification limit is being approached. This is especially true when the data is being used to establish compliance (of the body being represented by the analysed sample) with a requirement. Normally, regulatory agencies have a great deal of interest, because results may pertain directly to enforcement of legislation and regulation

Regulators want laboratories and their clients to exercise the duty of care and the duty to warn. They are often ready to step in and take over the exercise of these duties whenever they see a performance gap.

If a result indicates an approach to a specification limit, the reported uncertainty will allow regulators to determine whether or not further testing is required, or if enforcement action is necessary. Given a regulatory specification limit of 1.0 mg/L of lead (Pb) in wastewater, one might think that a result of:

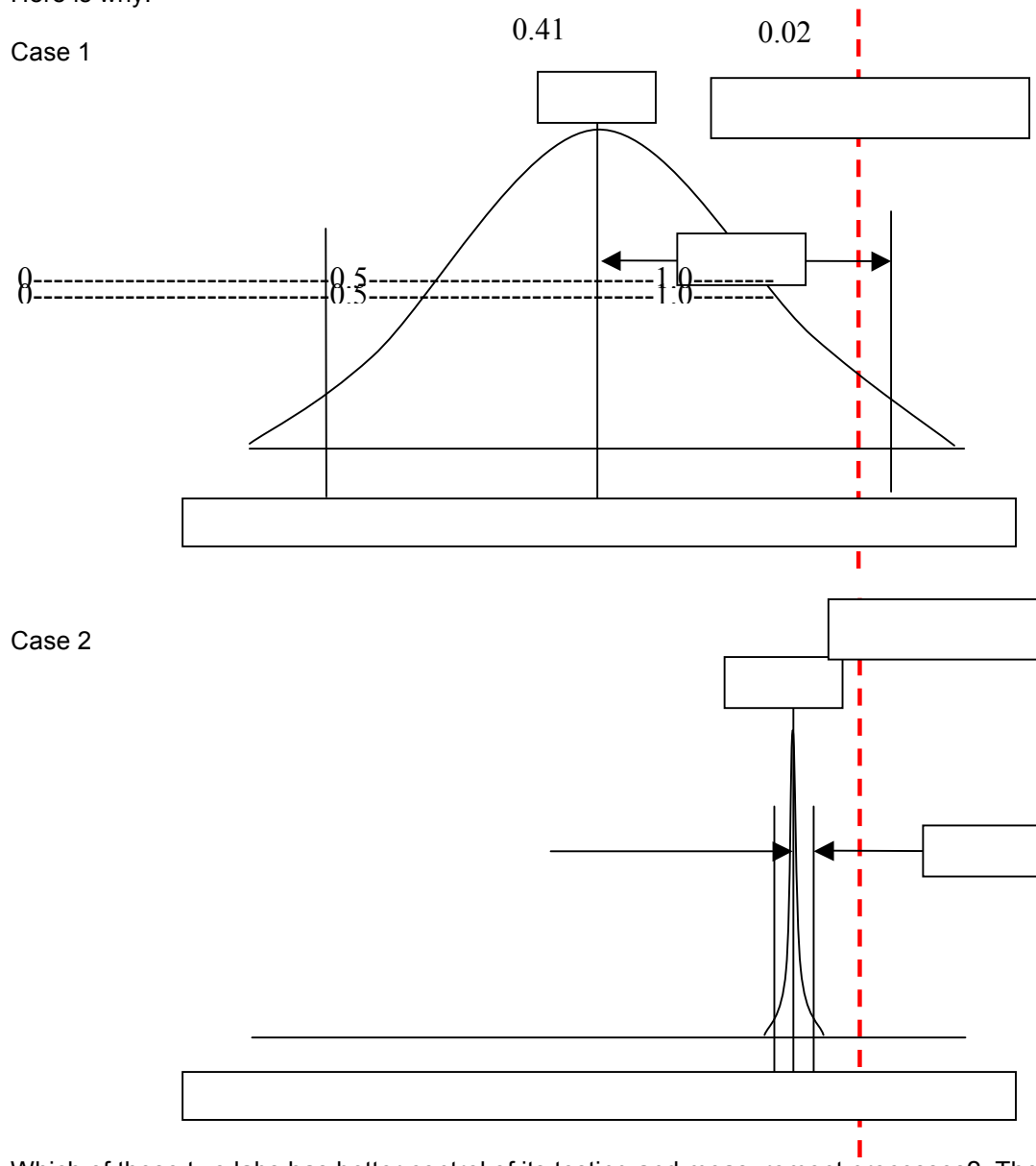
0.65 +/- 0.41 mg/L is better than

0.90 +/- 0.02 mg/L, but the regulators would disagree.

Specification Limit
0.65
0.90
Specification Limit

Here is why:

Case 1




Case 2



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

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 which demonstrate the better control of process (uncertainty) and the better control of traceability (trueness) would be considered more reliable. Uncertainty is a measure of the quality of a result.

## 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.

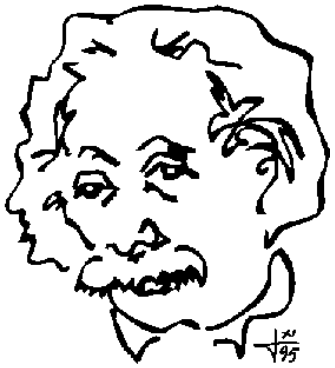
In accordance with ISO/IEC 17025:2005, laboratories are required to provide their estimates of uncertainty under the following conditions:

- 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 17025:2005 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.

## Uncertainty is a Client's Measure of Laboratory Quality

Remember our famous friend – the "lab guy?"



*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*

Remember the characteristics that engender trust in his work,

- Dedication to the science
- Concentration on consistency and competence,
- Understanding that there is no such thing as an "absolute result"

From the requirements given in ISO/IEC 17025:2005, and the principles behind the standard, this is a PERFECT lab

Other than those clients that may need uncertainties because a regulator now seeks 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 need 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

A client that asks for uncertainties because they are forced to, by a regulator needs no explanation. See the previous section on why a regulator would want to see it in the first place.

Sometimes clients may not want to be warned about a specification limit being approached, but if it is known, then the laboratory is duty bound to provide it. See the section on "duty to warn" above. The numbers may look good, but the uncertainties will help the client see through the rose-coloured glasses. If the client wishes to retain the rose-coloured glasses, see the previous section on regulators.

Finally, many clients want their results for specific reasons and although the idea of engaging them in a discussion on interpretation of results for validity or application may appear overkill, uncertainties are a quick method to help determine if the result is "fit for the purposes of the client." Looking for 0.2 micrograms per litre of an analyte in soil is not even worth reporting when the uncertainty of the method/result is +/- 20 micrograms per litre of the same analyte. If this discussion takes place before the contract is signed, the client will probably come back to the same lab when the desired outcome falls into the realm of achievable science.

### Uncertainty is a Lab's Measure of its own Quality

Other than the requirements given in ISO/IEC 17025:2005 on the estimation of uncertainties, laboratories that base their work on the use of the Scientific Method in the search for Objective Results (two of the

principles behind ISO/IEC 17025:2005), can make use of their own uncertainties as a significant indicator of their own quality of work. Calibration laboratories do this all the time.

Previous discussion on this topic has already focused on uncertainties being used to tell clients when a specification limit is being approached, or to tell clients about the validity of a result or its application.

The use of uncertainty to maintain traceability of measurement has also been discussed, but the day-to-day, matter-of-course investment that a laboratory makes in examining its own processes should also include the uncertainties estimated with measurements. When the components and contributions to the overall uncertainty of the measurement are examined, (or even listed in the order of their quantity) it can become very clear which parts of the process are the biggest contributors – and therefore the biggest headaches – in the work of the lab.
Identifying these sources allows a lab to focus directly on the potential problem areas and this is one of the precepts of continual improvement. "Fix the problems before they occur."

> "Quality flourishes where continual improvement is in place. It merely survives where there is no continual improvement."

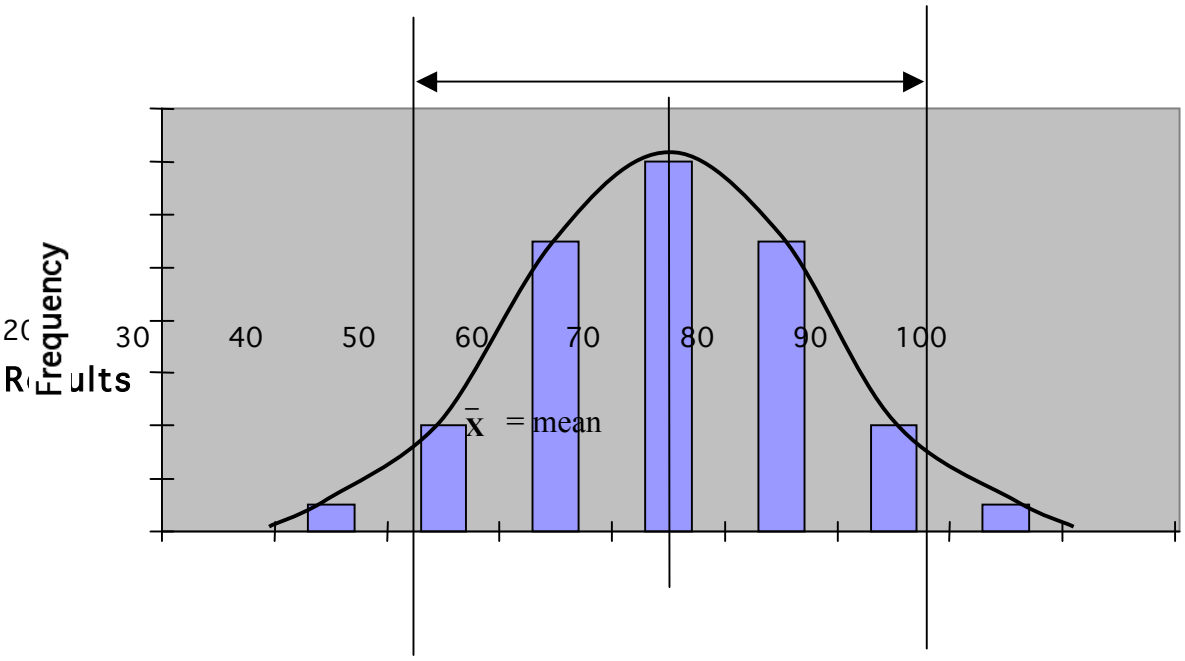
If the uncertainty associated with, for example, the reading of an instrument, is the single greatest uncertainty component of a result, then chances are that the procedure of reading the instrument, or modifying its display of data, is where effort will materially improve the process for the lab.

## Estimating uncertainties

Here are 46 results taken from a test or measurement to establish the value of something. For the purposes of this example, we will use concentration of some analyte, such as lead (Pb) in water, as the parameter under consideration.

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

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 concentration is 60.6 +/- 24 μg/L of analyte in water. 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 μg/L of analyte in water.

If you recall the MOST IMPORTANT question given earlier:

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

We now have an answer.

> We can be reasonably confident that 95% of all results of this sample will fall between 36.6 μg/L and 84.6 μg/L of analyte in water.

**Requirement to Report Uncertainties**

Testing laboratories are really only required to report their uncertainties under the following conditions:

- it is relevant to the validity or application of the test results,
- when a client's instruction so requires, or
- when the uncertainty affects compliance to a specification limit.

Outside of these three conditions, the decision to report uncertainties is entirely between the testing laboratory and its clients.

Calibration laboratories, on the other hand, are required to report the uncertainties associated with the range of measurement of the measurement parameter examined or provide a statement of compliance to a metrological specification – no exceptions. One or the other.

Overall, testing 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

### Demonstrating continuing Competence

Accredited laboratories are required to demonstrate their continuing competence on a regular basis. ISO/IEC 17025:2005, details the requirements for estimating and reporting uncertainties associated with tests and measurements.

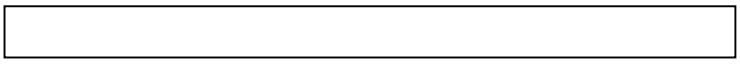
## Scientific certainty includes uncertainty of the result

### Certainty about the science

We know that laboratories and laboratory personnel can demonstrate competence and an understanding of their field of science. We know that this can be done through the process of accreditation.

Laboratory clients and regulatory authorities may not understand that such knowledge includes technical disciplines such as traceability of measurement and uncertainty of measurement.

Uncertainty is closely linked to traceability and is based on the following concept.



For example, the speed of light, *c*, the acceleration due to gravity, *g*, and the relationship between the circumference of a circle and its diameter, *pi*, are all considered constants in some form or other in science. *Pi* is a physical parameter and has been determined to many, many, many decimal places. *c* is fairly well characterised and *g* depends entirely on the physics between the two bodies considered (ie: you and the earth).

These quantities have been determined through experiment and derivation, but whenever they are measured, the measurement introduces an uncertainty to the result. Uncertainty does not change the value of the constant, but it provides us with some confidence in the measured result.

### Uncertainty of the Result

Measurement uncertainty provides an indication to the user of the data, that the result was produced in a manner that demonstrates competence. This includes control of all the processes that led to the actual result.

However, no measured quantity is absolute.

This is not intuitively obvious to engineers. Engineers live by design tables and the values and constants derived for engineering work:

*"Whaddya mean +/- 0.5? There were only **TWO** bricks!!"*

Uncertainty provides us some method of telling us how close the results are to each other and to the "truth." Uncertainty is not a measurement itself. It is an **estimate only** and it provides a good indication of the quality of the measured value.

Uncertainty:

- **is not** about "being sure" or "not being sure"
- **is** about establishing a region about the result (a range of values) to which we can mathematically (with some certainty) assign a level of CONFIDENCE

## 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,

*"…..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. _____, 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._____. Your Honour, the prosecution rests its case."*

# SECTION 13 - TRACEABILITY

## Requirements of ISO/IEC 17025:2005

In order for users of laboratory data to have confidence in that data, they seek comfort that the measurements used to produce the results are "traceable." Traceability can mean many things to many people, but to an accredited laboratory, it is very specific.

Traceability means that the laboratory measuring instrument was compared to other instruments which, in turn were compared to others, and so on… all the way back to a national measurement laboratory - and that the results of those comparisons produced a *Calibration Certificate* which describes certain properties about the measuring instrument.

The only property of a measuring instrument that counts, in considering traceability, is "uncertainty." Test results, in order to be traceable, must be conducted using traceable instruments only.

Only those instruments that have been competently compared to others of known uncertainty (calibrated) can have their contribution to the overall uncertainty of the measurement objectively examined. When this condition is met, the measurement is considered traceable. If the instruments are not traceable, then the test result is not traceable.

## 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???….."*

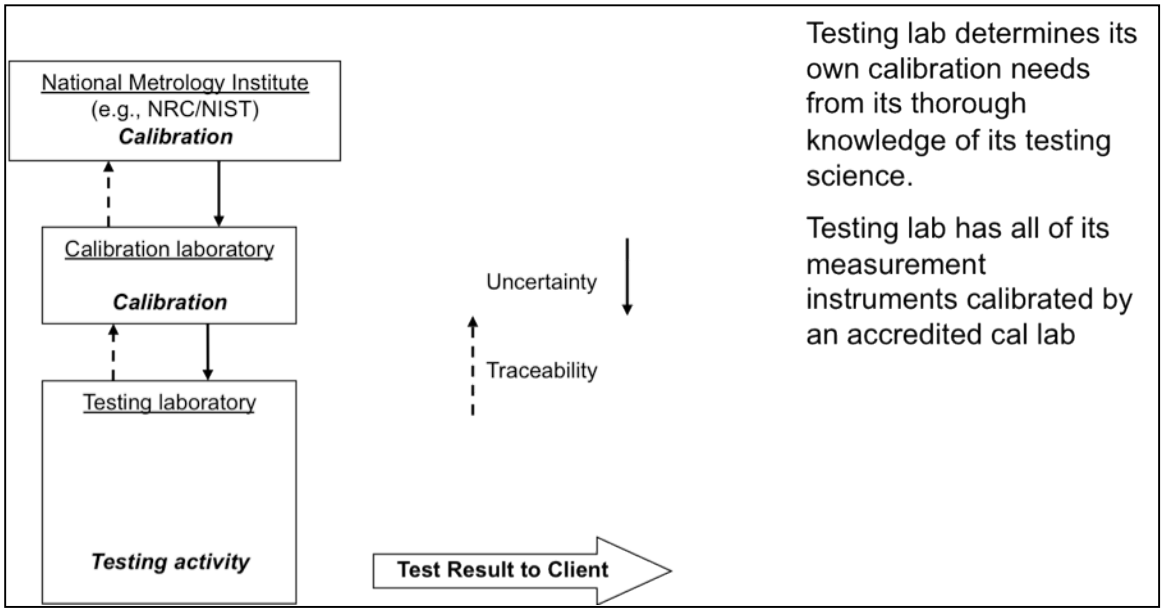
Traceability involves the competent propagation of uncertainties all along the chain of measurement from National Standard to the test result produced by a testing laboratory. If uncertainties have not been propagated to the actual test result, the result is not traceable. If it is not traceable, then its "precision" and "uncertainties" may appear OK, but its "trueness" will always be suspect.

## Uncertainty is the only result of calibrations.

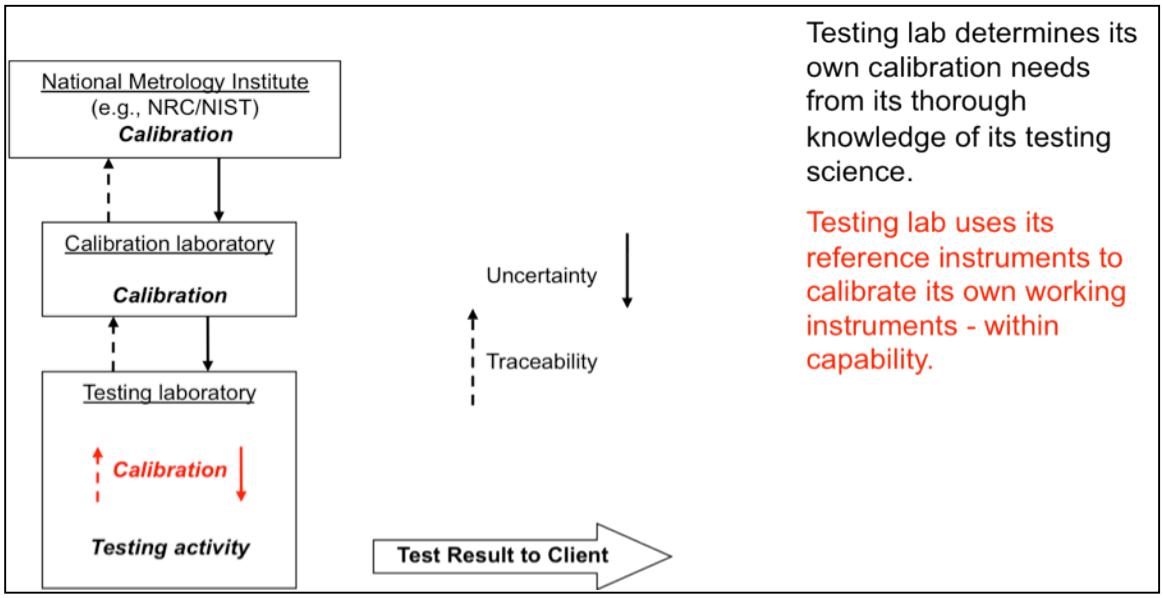
Testing laboratories produce test results. The test result is the product of a process of sampling and measuring.

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 will result in a statement that it is capable of producing measurement results within specific uncertainties for each range of measurement included in the calibration process. The result of calibration is, therefore, the set of uncertainties associated with the artefact calibrated.

## What does traceability look like?




OR – It looks like this….



At the top of this diagram are the National Metrology Institutes (NMIs) that are responsible in each nation for quantifying specific parameters for use within their nation. Most NMIs (such as Canada's National Research Council Institute for National Measurement Standards *NRC/INMS* or the National Institute of Standards and Technology *NIST* of the United States) have agreed on the *equivalence* of each other's measurements. This agreement is a multilateral recognition arrangement MLA (or mutual recognition arrangement MRA) established by the International Committee for Weights and Measures – *"Comite Internationale des Poids et Mesures*" (CIPM).

The agreement is to establish equivalence based on "demonstrated competence, " in part using accreditation against ISO/IEC 17025:2005

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

Within each NMI is the ability to conduct measurements with very small uncertainties, in support of the MRA, and in support of measurement science research. They are also able to calibrate the instruments from calibration laboratories seeking to establish traceability at the level of the NMI. This is the start of the traceability chain for a testing laboratory.

## Uncertainty can help a lab control its traceability (calibration) costs

The final chapter in the saga of the "Traceability Chain" is the use of calibrated instruments in the measurements made for testing. All accreditation bodies provide their own policies regarding the traceability of measurements produced by accredited laboratories.

ISO/IEC 17025:2005 requires the owner laboratory to decide the frequency of calibration of all of their instruments. Many laboratories have become used to simply having all their instruments calibrated annually. Some laboratories also wish the calibration laboratory to decide the frequency of calibration. The standard makes it clear, however, that the owner laboratory must develop a method of examining its own calibration frequency requirements - not the calibration lab.

There are two reasons for this:

1. Cal labs should not be allowed to influence their own clients on recurring business, and
2. Test labs must be able to understand, in technical terms, the effect of their own instruments on the output of their work – the results.

There is no technically valid reason for requiring a calibration cycle of 12 months without the data to back up such a decision. While experience teaches us that this is a relatively safe default condition, it is far from reliable.

The only technically valid reason for the establishment of a calibration cycle for any instrument is *comparison of the uncertainties it delivers to the overall measurement in comparison with the uncertainties that are needed.*

For example, if a thermometer is calibrated to +/- 0.1$^{o}$C and the uncertainty of the measurement requires the thermometer to deliver +/- 0.1$^{o}$C, then there is good evidence to having that thermometer calibrated every six months or so, in order to ensure it continues to deliver the same uncertainties. It is operating on the line and needs to be monitored.

If the uncertainty of the measurement requires the thermometer to deliver +/-1.0$^{o}$C , then it is performing one order of magnitude (ten times) better than is needed. There exists sufficient evidence to have it calibrated only once every year.

If the uncertainty of the measurement requires the thermometer to deliver +/-5.0°C , then it is performing greater than one order of magnitude better than is needed. There exists sufficient evidence to have it calibrated only once every two years or so.

Now this example may be debated by different temperature measurement experts, but the simple fact is that the better an instrument performs, in comparing its calibrated uncertainties with the uncertainties demanded by the measurement process, the less frequently it needs to be calibrated. Laboratories that can establish this relationship will save themselves money.

The choices to a laboratory are the following:

- When instrument performance is **very much better than the requirement**, the laboratory can reduce the calibration frequency (extend the cycle time).
- When performance is at the **same level as requirement**, the calibration frequency must be increased, OR ……
- When the laboratory does not know, they must calibrate that equipment once per year.

# SECTION 14 – CONCLUSION

This guide is longer than the standard. The authors of the standard mistakenly assumed that persons working in laboratories would have the same knowledge on all subjects that the members of committee enjoyed. This was an unsafe assumption. That is why this guide was created – to partially fill the gap.

If one remembers that the technical considerations in ISO/IEC 17025:2005 are far more important than the management system ones, it becomes easy to see why a guide of this type devotes two-thirds of its text to technical issues.

Comments are always welcome. This text was written to assist laboratories better understand ISO/IEC 17025:2005 and its implementation. Such a document needs user input in order to remain useful.

Please direct comments to:

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