Evaluating Method Validation

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Why Test?

Test results allow us to make better decisions concerning

- quality of a product or service offering
- health & safety decisions
- environment decisions

Characteristics of a test result

A test result should be reliable, meaningful and consistent

- Meaningful - Customers application of the results.
- Consistent – Ability to reproduce the results again under similar conditions and get results within an acceptable error margin.
- Reliable – Ability to produce valid results

Selecting a test method

(Descriptive, qualitative & quantitative methods)

- Customer needs
- Capability and resources required to conduct the test
- Costs to conduct the tests (eg. Reagents, reference standards..)
- Safety of laboratory staff to conduct the test
- Speed or turnaround time required
- Sample type and size for storage, preparation & handing
- Equipment required
- Extent of Validation required

Demonstrating your selection

Scientific objective evidence:

- Limit of detection
- Limit of quantitation
- range
- Linearity and sensitivity
- Accuracy
- Precision
- Selectivity/specificity
- Robustness/Ruggedness

What type of methods should a laboratory validate?

A laboratory should validate **all** methods including protocols (eg. Sampling protocol, sub-sampling protocol)

Note: The extent and type of validation may differ.

ISO 17025:2005

5.4 Validation is the confirmation by examination and the provision of objective evidence that the particular requirements **for a specific intended use** are fulfilled.

5.4.5.2: The laboratory shall **validate** non standard methods, laboratory-designed / developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods, to confirm that the methods are fit for their intended use. The **validation** shall be extensive as is necessary to meet the needs of a given application or field of application.

ISO 15189:2007

5.5.1**:** … If in-house procedures are used, they shall be appropriately validated for their intended use.

5.5.2: The laboratory shall use only validated procedures for confirming that the examination procedures are suitable for the intended use. The validations shall be as extensive as are necessary to meet the needs in the given application or field of operation. The laboratory shall record the results obtained and the procedure used for the validation.

ISO 15189:2007

4.6.2: Purchased equipment and consumable supplies that affect the quality of service shall not be used until they have been verified as complying with standard specifications or requirements defined for the procedures concerned. This may be accomplished by examining quality control samples and verifying that results are acceptable. Documentation of the supplier's conformity with its QMS may also be used for verification.

Factors that impact on validation:

- Reference standards & traceability
- The nature of the measurand.
- The nature of the matrix in which the measurand is tested.
- The environment and support services. e. Sampling, sample handling.
- Conditions of samples and reagents.
- Instruments and equipment and their calibrated status.
- Reagents and reference material purity, homogeneity and stability. i. Recovery from matrix and sample stability.
- computational effect.
- Operators training and know how.

Factors that impact validation:

- Validation studies of a test method should be conducted using the same matrix, equipment, reagents, personnel, site, support systems and software as those intended for the conduct of routine test.

- Maintenance of an uninterrupted chain of traceability is an absolute requirement for the demonstration of a method validity.

Assessments –
Seeing the big picture

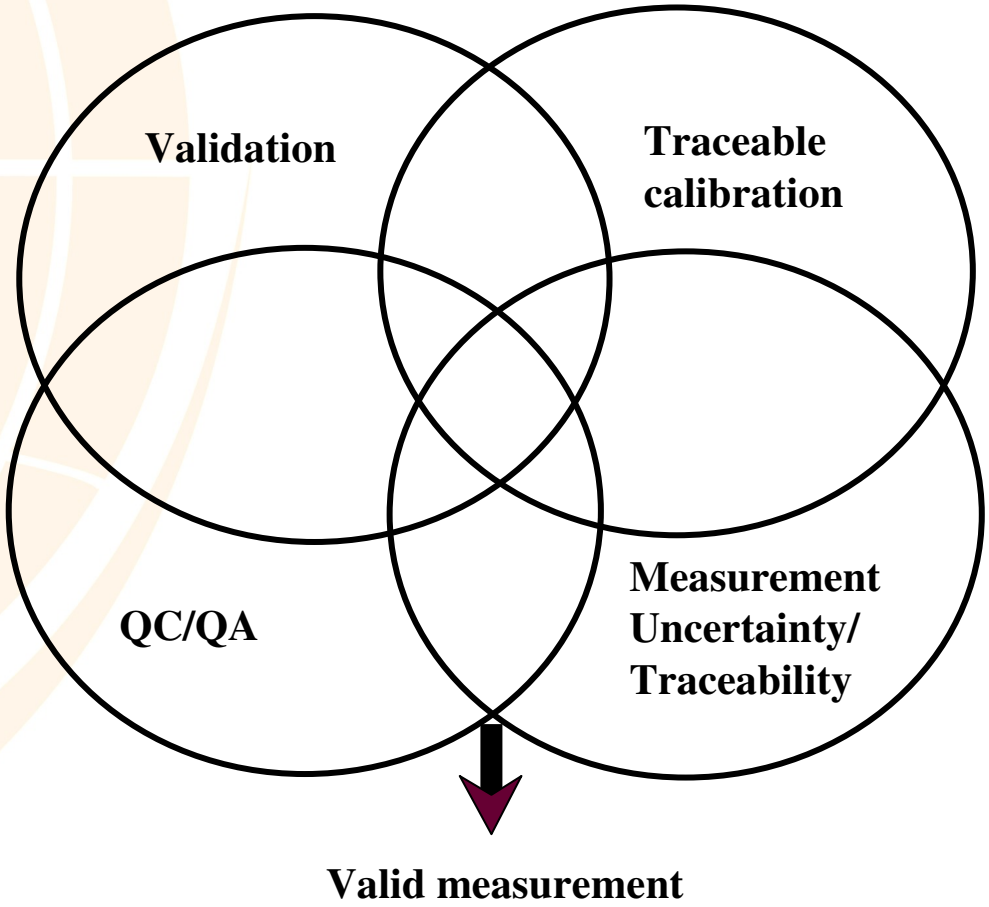
In terms of ISO 17025 & ISO 15189,
the laboratory should be able to demonstrate objectively with evidence
their capability of performing the method
within appropriate validation ranges
consistently & reliably
and provide the customer
with meaningful results.

What is a valid measurement

A valid measurement may be assured when (ILAC G9:2005):

- Validated methods are used
- Traceability of measurement to the SI units are ensured by equipment calibration
- Qualified and competent staff undertake the work
- Comparability with measurements made in other laboratories is assured (traceability and measurement uncertainty via use of reference materials or reference standards)
- Independent evidence of performance is available (proficiency testing)
- Well defined quality control procedures are employed

Figure 1: Overlap between functions associated with Measurement Traceability and Analytical Quality (ILAC G9:2005)



Evaluating validation

- How are test methods selected by the laboratory?
- Is the laboratory knowledgeable about best practices for validation in the applicable discipline and do they have access to relevant documents? Is the client providing any information?
- Does the laboratory have procedures for assuring the quality of test results generated by test methods?
- Does the laboratory check on factors that impact on validation (eg. Reference standards & traceability, support services, Sampling, sample handling, Instruments and equipment and their calibrated status, Operators training and know how.)

Evaluating validation

- Who is assigned responsibility for validations? Are staff trained to conduct validations and evaluate data packages?
- Is there a separation in the technical records between method development and validation?
- Is the validation documentation package complete?
- Is there evidence that the method has been successfully transferred to routine use, transferred to another laboratory or undergone some type of peer review, where appropriate?

Evaluating validation

- Is there a process to review performance data generated for test methods in routine use to demonstrate to clients the ongoing fitness for purpose?

- Is the method declared fit for purpose?

Non-conformances raised by Assessors

- Lab states that we are using standard methods therefore there is no need to validate methods
- No validation available (initial assessment)
- PT results passed off as validation
- No acceptance/rejection criteria for data from validation study
- No summary statement on fitness for purpose
- No trending of QC data against validation ranges that has been established

Non-conformances raised by Assessors

- Lack of measurement traceability
- Failure to revalidate when making changes that affect the method (equipment change, reference standard change) or when customer needs change
- Loss of key staff and lack of training of other staff on validation

Questions

Thank You

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