## SELECTION, VERIFICATION AND VALIDATION OF METHODS

**Basic**
Definition and requirements for selection, verification and validation of methods are given in section 3.8, 3.9. and 7.2 of ISO/IEC 17025:2017.

***Verification:***
***Standard methods need verification to ensure that the laboratory is capable of performing the stated activities. Verification is the demonstration that the laboratory is capable of replicating, with an acceptable level of performance, a standard method. Verification under conditions of use is demonstrated by meeting system suitability specifications established for the method, as well as a demonstration of accuracy and precision or other method parameters for the type of method. See JCGM200:2012 - §2.44 for additional details and examples***

***Validation:***
***ISO/IEC 17025: 2017 – Clause 7.2.2.1: "The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. … "***
***See JCGM200:2012 - §2.45 for additional details and examples***

**Factors to consider**

**Selection:**
Customer could specify the method to be used, otherwise, the laboratory can select an appropriate one and inform the customer.

Customer acceptance is usually given in written form; agreement can be part of the contract.
When a deviation from the method occurs, the deviation shall be notified to the customer unless a specific statement has been already included as part of the contract.
Deviation from a standard method requires validation of the method.

**Verification:**
Verification should be documented in such a way to provide evidence that the laboratory is capable of achieving the required performance characteristics of the method; this can include:

- Estimation of repeatability and/or reproducibility
- Instruments characteristics
- Operator qualification (training, experience, competences, …)
- Environmental conditions
- Materials or reagents
- Any other characteristics that could influence the result

General cases are listed below:

- *Methods in national or international standards* should be regarded as validated. Nevertheless, it must be verified that all conditions are fulfilled in the laboratory's application. This includes the stated uncertainty. If the uncertainty of the result is not mentioned or stated in the national or international standard, some reflection about this should be made by the laboratory using it.
- *Seldom used methods.* When a method is used only occasionally, the maintenance of personal competence or the fitness of the equipment may be questioned. Here a reasoning should be made, considering e.g. the experience and education of the personnel in areas close to the method in question or the straightforwardness of the method.

Example: When testing the strength and deformations of 24 feet containers once every second year, the verification should consider whether the personnel has extensive training in mechanics or solid mechanics, and whether other large scale mechanical tests are regularly performed in the laboratory.

**Validation:**
When planning a validation much work can be saved by having technical competence available and by use of a systematic approach. One aim is to judge which factors are of most importance and deserve most attention. Three main stages could be used:

- Distinguish between method of test, and of producing and processing the specimen, including sampling
- Consider the test or measurement factors (equipment and calibration, handling of specimen, testing or measurement procedure, analysis and form of results)
- Consider supplementary changing factors (environment, education and experience of operator, frequency of use of the method)

***The documentation should clearly describe which factors are of significance and why, and how they are treated in the validation. Conditions and limitations should be described.***

Note: One important distinction is that a method may be valid, but not necessarily relevant, e.g. the result is what is stated, but does not tell what is really needed. Many examples may be found in old but still used standards for product testing.

**The two main principles for validation**
Validation may be obtained using the following principles, often in combination.

- Use scientific knowledge and acknowledged experience to describe and demonstrate the validity of factors involved.

Example: Time to obtain thermodynamic equilibrium in a climate chamber may be assessed either by dimensional analysis of the laws of heat flow, or by experience from measurements in similar situations.

- Use, if possible, interlaboratory comparison, proficiency tests or reference materials to show that the complete chain of testing or analysis gives the stated result, including uncertainty, and in the range of interest.

Example: Chemical analyses by "black box" equipment may be validated by reference materials and proficiency tests.

**Different types of methods**
The validation procedure should be chosen in accordance with the actual type of method.

*Method extensions* or *variation of methodologies* are very important for services to innovative branches of industry. For efficient accreditation of *flexible scope*, such validation is important. It is recommended to use scientific knowledge or experience. Good competence of laboratory staff is essential.

Example: EMC investigations in increasing ranges of frequencies require both a scientific basis and experience from the actual anechoic chamber in order to judge the necessary number of geometries and antenna configurations to achieve the resulting uncertainty.

*In-house methods* have to be validated by the laboratory, but with consideration of a cost-benefit perspective and in agreement with the customers. Often the method is an extension or a simple combination of known methods.

Example: The torque required to open the lid of a can may be tested in a simple way with an uncertainty of, say 3 per cent, but it may be very difficult to achieve an uncertainty of 1 per cent. If the variation in torque between cans is typically 10 per cent and the intention is to check the possibility for elderly people to open the cans, the 3 per cent is obviously sufficient.

***Validation is a relative concept and the extent should always be chosen with consideration of the intended use of the results. This is implicit in the paragraph 7.2.2 cited above.***

**New Method**
According to the above, each new method has to be validated or verified prior to the implementation. Both validation and/or verification have to be documented and approved.

**Uncertainty fit for purpose as part of the validation procedure**
Uncertainty assessment may seem complicated and is not always possible. There are most often simple ways to obtain robust assessments of uncertainty. A continuously updated list of useful documents is available on the EUROLAB web-site (www.eurolab.org) (for reference use the GUM).

If possible the definition of instrumental uncertainty and target uncertainty could be included for the assessment (concepts described in the VIM).

Some rules of thumb may be the following.

- One may distinguish between dispersion in the tested objects (the representativity of a sample), and the dispersion (uncertainty) of the test method.
- Selection of Type A and Type B should be made according to the quality of the contribution.
- If Type B estimates have to be used and combined, it is important to find the ones contributing most.
- The others (smaller than 5% of the biggest one) can normally be discarded.

In e.g. chemical analysis, a local uncertainty measure, *repeatability,* is used for controlling stability of production processes etc., which may contain *bias, systematic error* contributing to the global uncertainty. In other areas, as products intended for safety-critical applications, it is necessary to use the global uncertainty, relating results to the true value.

A concept related to this is the *reproducibility* describing for, typically, a number of laboratories and operators the capability to produce similar results over time applying the method.

Note: The ISO/IEC 17025 standard mentions a number of measures of properties of a test method, as robustness, sensitivity, detection limit etc. where the terms are sector specific and should be considered if need be by finding their definition in the VIM.

See also:
JCGM 100 (GUM)
JCGM 200 (VIM)