

## **Abstract from a QM-Handbook acc. ISO 17025**

### **5.4 Test and calibration methods and method validation**

#### **5.4.1 General**

The Lab uses appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test data.

The laboratory has instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing where the absence of such instructions could jeopardize the results of tests and/or calibrations.

All instructions, standards, manuals and reference data relevant to the work of the laboratory are kept up to date and made readily available to personnel (see 4.3).

Deviation from test and methods occur only if the deviation has been documented, technically justified, authorized, and accepted by the client.

ISO NOTE: International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.

The defined standards and specifications regularly contain sufficiently precise information how to perform the tests. In addition, special SOP's are available with additional details. Standards and SOPs are available through the QM Control Matrix. Maintenance and control of update status of these documents is within the responsibility of the Lab Manager. The update service only covers documents on the server.

#### **5.4.2 Selection of methods**

The LAB uses test methods, including methods for sampling, which meet the needs of the client and which are appropriate for the tests it undertakes. Methods published in international, regional or national standards are preferably used. The LAB ensures that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard is supplemented with additional details to ensure consistent application.

When the client does not specify the method to be used, the LAB selects appropriate methods that have been published either in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use

and if they are validated. The client will be informed as to the method chosen. The laboratory confirms that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes the confirmation will be repeated.

The LAB will inform the client when the method proposed by the client is considered to be inappropriate or out of date.

The test procedures used by the LAB are listed with precedence in the standards acc. to the range LAB's accreditation.

### **5.4.3 LAB-developed methods**

The introduction of test methods developed by the laboratory for its own use is a planned activity and is assigned to qualified personnel equipped with adequate resources. Plans shall be updated as development proceeds and effective communication amongst all personnel involved will be ensured.

### **5.4.4 Non-standard methods**

When it is necessary to use methods not covered by standard methods, these will be subject to agreement with the client and will include a clear specification of the client's requirements and the purpose of the test and/or calibration. The method developed will have been validated appropriately before use.

They contain at least the following information:

- a) appropriate identification;
- b) scope;
- c) description of the type of item to be tested or calibrated;
- d) parameters or quantities and ranges to be determined;
- e) apparatus and equipment, including technical performance requirements;
- f) reference standards and reference materials required;
- g) environmental conditions required and any stabilization period needed;
- h) description of the procedure, including
  - affixing of identification marks, handling, transporting, storing and preparation of items,
  - checks to be made before the work is started,
  - checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use,
  - the method of recording the observations and results,
  - any safety measures to be observed;
- i) Criteria and/or requirements for approval/rejection;
- j) Data to be recorded and method of analysis and presentation;
- k) The uncertainty or the procedure for estimating uncertainty.

### 5.4.5 Validation of methods

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

Non-standard methods, laboratory-designed/ developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods are validated to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.

The techniques used for the determination of the performance of a method should be one of, or a combination of, the following:

- calibration using reference standards or reference materials;
- comparison of results achieved with other methods;
- inter-laboratory comparisons;
- systematic assessment of the factors influencing the result;
- assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

ISO NOTE: When some changes are made in the validated non-standard methods, the influence of such changes should be documented and, if appropriate, a new validation should be carried out.

The range and accuracy of the values obtainable from validated methods

- the uncertainty of the results,
- detection limit,
- selectivity of the method,
- linearity,
- limit of repeatability and/or reproducibility,
- robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object,

as assessed for the intended use, shall be relevant to the client's needs.

Validation includes

- specification of the requirements,
- determination of the characteristics of the methods,
- a check that the requirements can be fulfilled by using the method, and
- a statement on the validity.

Validation is always a balance between

- costs,
- risks and
- technical possibilities.

There are many cases in which the range and uncertainty of the values (e.g. accuracy, detection limit, selectivity, linearity, repeatability, reproducibility, robustness and cross-sensitivity) can only be given in a simplified way due to lack of information.

The LAB is an active member of the "ISSS Accuracy Panel" which deals with validation, precision and comparison tests of existing and new test procedures.

#### **5.4.6 Estimation of uncertainty of measurement**

As a testing laboratory performing its own calibrations, the LAB has and applies a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.

The LAB has and applies procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid calculation of uncertainty of measurement. In these cases the LAB attempts to identify all the components of uncertainty and make a reasonable estimation, and ensures that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.

ISO NOTE 1: The degree of rigor needed in an estimation of uncertainty of measurement depends on factors such as:

- the requirements of the test method;
- the requirements of the client;
- the existence of narrow limits on which decisions on conformance to a specification are based.

ISO NOTE 2: In those cases where a wellrecognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions (see 5.10).

When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

ISO NOTE 1: Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

ISO NOTE 2: The predicted long-term behaviour of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.

ISO Note 3: For further information, see [ISO 5725](#) and the **Guide to the Expression of Uncertainty in Measurement**

#### **5.4.7 Control of data**

Calculations and data transfers are subject to appropriate checks in a systematic manner.

Since computers are used for the acquisition, processing, recording, reporting, storage or retrieval of test data, the laboratory ensures that:

- a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;
- b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;
- c) computers are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity