Activity 1.5 ME

Work in new areas

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ISO/IEC 17025:2005

in

Pharmacological laboratories

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Clause 5.4.2: Selection of methods

The laboratory shall use test methods, including methods for sampling, which meet the needs of the customer and which are appropriate .

Methods published in international, regional or national standards shall preferably be used.

The laboratory shall ensure that it uses the **latest valid edition** of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.

When the customer does not specify the method to be used, the laboratory shall select 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 customer shall be informed as to the method chosen.

The laboratory **shall confirm** that it can properly operate standard methods before introducing the tests. If the standard method changes, the confirmation shall be repeated.

The laboratory shall inform the customer when the method proposed by the customer is considered to be inappropriate or out of date.

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Clause 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.

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Clause 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 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.

Note 1: Validation may include procedures for sampling, handling and transportation.

Note 2: 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;
- interlaboratory 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.

Note 3: 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.

Clause 5.4.5.3

The range and accuracy of the values obtainable from validated methods (e.g. 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 customers' needs.**

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Clause 5.4.5.3 Notes

Note 1: 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.

Note 2: As method-development proceeds, regular review should be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan should be approved and authorized.

Note 3: 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.

Clause 5.4.6.1 Estimation of Uncertainty

A testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement .

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Clause 5.4.6.2

Testing laboratories shall have and shall apply 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 laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure 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.

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Clause 5.4.6.2 Note

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 customer;
- **the existence of narrow limits on which decisions on conformity to a specification are based.**

Note 2: In those cases where a well-recognized 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 .

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Clause 5.4.6.3

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.

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.

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.

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Clause 5.6.1 Measurement Traceability

All equipment used for tests, including equipment for **subsidiary** measurements (e.g. for environmental conditions) **having a significant** effect on the accuracy or validity of the result of the test, calibration or sampling **shall be calibrated before being put into service**. The laboratory shall have an established programme and procedure for the calibration of its equipment.

Note 1: Such a programme should include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

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Clause 5.6.2.1/5.6.2.2 Testing Laboratory

For testing laboratories, the requirements given in 5.6.2.1 apply for measuring and test equipment with measuring functions used, unless it has been established that the associated contribution from the calibration contributes little to the total uncertainty of the test result. When this situation arises, the laboratory shall ensure that the equipment used can provide the uncertainty of measurement needed.

Where traceability of measurements to SI units is not possible and/or not relevant, the same requirements for traceability to, for example, certified reference materials, agreed methods and/or consensus standards, are required as for calibration laboratories .

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Clause 5.6.3.2 Reference Materials

Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked as far as is technically and economically practicable.

Clause 5.6.3.3 Intermediates Checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out according to defined procedures and schedules.

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Clause 5.9.1 Assuring quality

The laboratory shall have **quality control procedures** for **monitoring the validity** of tests undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, **statistical techniques shall be applied** to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

a) **regular use** of certified reference materials and/or internal quality control using secondary reference materials;

b) participation in interlaboratory comparison or proficiency-testing programmes;

c) replicate tests or calibrations using the same or different methods;

d) retesting or recalibration of retained items;

e) correlation of results for different characteristics of an item.

The selected methods should be appropriate for the type and volume of the work undertaken.

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Clause 5.9.2

Quality control data **shall be analysed** and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.

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