A011
Guidelines for checking and validating test, calibration and medical biology methods according to ISO/IEC 17025 and ISO 15189

Modifications: p. 6

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1. Aim

These guidelines set out the items that audited laboratories must provide as part of an accreditation audit to meet the requirements of standards ISO/IEC 17025 and ISO 15189 relating to the verification/ confirmation and validation of test, calibration and medical biology methods submitted for accreditation.

When laboratories make use of in-house developed methods, their validation is an essential step. To strengthen the implementation of this practice, OLAS accreditation is only granted on condition that the validation stage has been completed at the time of the audit for obtaining or extension of accreditation.

2. Summary of requirements

The standard ISO/IEC 17025:2017 (§ 7.2.1.5, 7.2.2.1 and 7.2.2.2) stipulates that:

"The laboratory shall **verify** that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. Records of the verification shall be retained. If the method is revised by the issuing body, verification shall be repeated to the extent necessary."

"The laboratory shall **validate** non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.

NOTE 1 Validation can include procedures for sampling, handling and transportation of test or calibration items.

NOTE 2 The techniques used for method validation can be one of, or a combination of, the following:

a) calibration or evaluation of bias and precision using reference standards or reference materials;
b) systematic assessment of the factors influencing the result;
c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;
d) comparison of results achieved with other validated methods;
e) interlaboratory comparisons;
f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method."

"When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed."

Standard ISO 15189:2012 (§5.5.1) stipulates that:

"The laboratory shall select examination procedures which have been validated for their intended use."

"Validated examination procedures used without modification shall be subject to independent **verification** by the laboratory before being introduced into routine use."

"The laboratory shall **validate** examination procedures derived from the following sources:

a) non-standard methods;
b) laboratory designed or developed methods;
c) standard methods used outside their intended scope;
d) validated methods subsequently modified.

The validation shall be as extensive, as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled.

NOTE Performance characteristics of an examination procedure should include consideration of: measurement trueness, measurement accuracy, measurement precision including measurement repeatability and measurement intermediate precision; measurement uncertainty, analytical specificity, including interfering substances, analytical sensitivity, detection limit and quantitation limit, measuring interval, diagnostic specificity and diagnostic sensitivity."

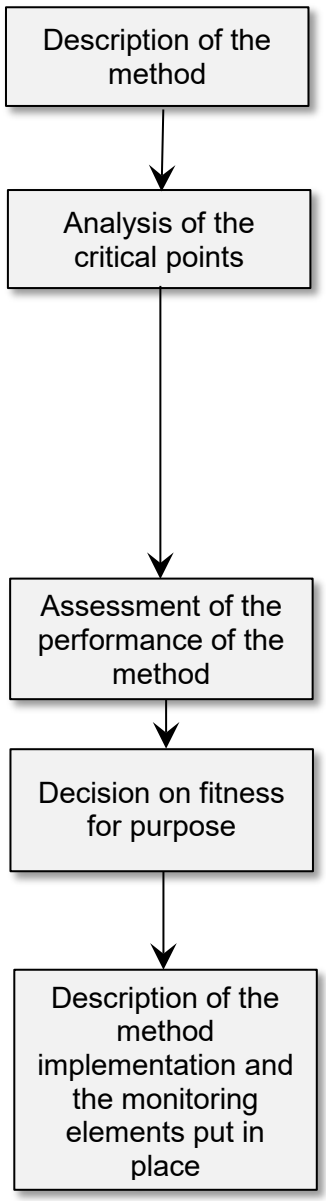
From these ISO/IEC 17025 and ISO 15189 requirements, we can deduce that:

- if a standard method is used by the laboratory must be **verified** to ensure its correct application by the laboratory and,
- if a method that is not standardised is used by the laboratory, it must be **validated** by the laboratory.

3. Validation files

Items which lead to method verification or validation must be kept together in a file available to the technical auditors who may request it before the laboratory audit or examine it during the audit.

This allows to trace the main steps of the validation, as described below:



The methods used must be documented (principle of the method, samples, reagents, detailed operating procedure, used for verification/confirmation or validation…).

A step by step analysis of the process allows for instance:

- to confirm the strict following of the prescriptions and the procedure of the standardized /recognised method;
- to identify, where appropriate, deviations from the standardised /recognised method;
- to identify the critical points of the process;
- to identify the points that require experimental verification of the performance of the method.

The performances of the method that need to be assessed depend on the circumstances analysed above (refer to the tables in chapters 4.1 à 4.3).

The file must conclude on the fitness for purpose of the method or the analytical system for the defined or examined field of application.

Updating the validation file and enriching it with the continuous validation data is essential. Use of the results of internal quality controls and external quality assessments allows confirming the precision and trueness of the method.

If the field of application of the method is to be extended, provisions on how to complete the validation file must be specified by the organism.

A template (of non-mandatory use) for a method validation or verification file for medical analyses is provided in the form *F044 – Template for a validation/verification file of a medical analysis method*.

4. Performances to be evaluated

Verification involves determining the characteristics of the standard method as applied within the laboratory and checking, where appropriate, that these characteristics are consistent with those defined by the standard method or with those determined by the Chief Laboratory Technician.

Validation of a non-standard method requires evaluation of additional characteristics. The purpose is to determine the characteristics of the methods as it is used within the laboratory, in order to check, if appropriate, that these characteristics are consistent with those defined by the standard method or with those determined beforehand by the Chief Laboratory Technician or the client. He may rely on a bibliography, if possible independent of the equipment or reagent supplier, shall endeavour to carry out on-site experimental verifications.

It is the responsibility of the technical auditors to define within their area of competence whether the method is standard or not. Indeed, these (methods) may also be defined in regulations, or even in international and scientific journals, which can give them the status of “reference standard”.

Equally, the laboratory must document possible deviations in application from the standard/ recognised method[1] and prove that these deviations do not alter method performance. In case of "minor” modifications to a recognised or standardised method, the validation must be adapted to the needs and will not necessarily be as advanced as for a newly developed method.

In any case, participation in inter-laboratory tests, if they exist, is essential to ensure the control over time of the method[2].

The tables hereafter summarise the characteristics to evaluate for testing (chapter 4.1), calibration (chapter 4.2) and biomedical (chapter 4.3) methods. Depending on the methods or application fields, the assessment of certain characteristics may be not applicable or solely realised through a bibliographic study.

Definitions relating to the topic are presented in the annex.

[1] This will then be identified as « internal method ~~according to~~ based on ISO… » in the accreditation scope.

[2] See document *A015 – Proficiency Testing by Interlaboratory Comparisons* concerning the policy of OLAS regarding participation in interlaboratory comparisons.

4.1 Case of testing methods – ISO/IEC 17025

Characteristics to be evaluated	Quantitative methods		Qualitative methods	
	Verification of a recognised/ standard method	Method validation	Verification of a recognised/ standard method	Method validation
Identification and control of influencing factors / residual risks	X	X	X	X
Repeatability	X[3]	X	if appropriate	if appropriate
Intermediate precision	X	X	if appropriate	if appropriate
Inter-operator variability	if appropriate *(e.g. non-automated qualitative methods)*			
Trueness / Accuracy	X *	X *	N.A.	N.A.
Measurement uncertainty	X	X	N.A.	N.A.
Calibration function/ linearity domain	if appropriate	if appropriate	N.A.	N.A.
Recovery rate	if appropriate *(e.g. analytical chemistry methods)*		N.A.	N.A.
Detection limit	if appropriate	X	if appropriate	X
Limit of quantification	if appropriate	X	N.A.	N.A.
Analytical specificity	if appropriate	X	if appropriate	X
Decision threshold	if appropriate *(e.g. radiotoxicological analyses)*		N.A.	N.A.
Contamination	if appropriate *(in case of risk, depending on the situation (equipment qualification))*			
Robustness / ruggedness of the method and stability of the reagents	if appropriate	X	if appropriate	X
Comparison of methods	if appropriate *(e.g. alternative methods in microbiology)*			
Computer and calculation data	if appropriate *(at least for mon- and bidirectional transfers)*			

* e.g. interlaboratory comparisons, use of spiked samples and/or reference materials of known concentration if available.

[3] Not required for quantitative radionucleid analysis methods

4.2 Case of calibration methods – ISO/IEC 17025

Characteristics to be evaluated	**Quantitative methods**
	Verification of a recognised/ standard method Method validation
Identification and control of influencing factors / residual risks	X
Repeatability	X
Reproducibility	X
Trueness	X
Measurement uncertainty	X
Calibration function/ linearity domain	if appropriate
Comparison of methods	if appropriate
Computer and calculation data	if appropriate

4.3 Case of biomedical methods – ISO 15189

Characteristics to be evaluated	Quantitative methods		Qualitative methods	
	Verification of a recognised/ standard method	Method validation	Verification of a recognised/ standard method	Method validation
Identification and control of influencing factors / residual risks	X	X	X	X
Repeatability	X	X	N.A.[4]	N.A.[4]
Intermediate precision	X	X	N.A.	N.A.
Inter-operator variability	if appropriate *(e.g. non-automated qualitative methods)*			
Diagnostic sensitivity	if appropriate	X	if appropriate	X
Diagnostic specificity	if appropriate	X	if appropriate	X
Trueness / **Accuracy**	X *	X *	N.A.	N.A.
Incertitude de mesure	X	X	N.A.	N.A.
Reference interval	if appropriate	X	N.A.	N.A.
Decision threshold	if appropriate *(quantitative methods with qualitative interpretation)*		N.A.	N.A.
Measurement range - detection limit - limit of quantification - Upper limit of linearity	if appropriate *(e.g. troponin, micro albumin, platelets, PSA, TSH, …)*	X	N.A.	N.A.
Interferences	if appropriate	X	if appropriate	X
Contamination	if appropriate *(in case of risk, depending on the situation (equipment qualification))*			
Robustness / ruggedness of the method and stability of the reagents	if appropriate	X	if appropriate	X
Comparison of methods	if appropriate *(e.g. second analysers)*			
Computer and calculation data	if appropriate *(at least for mon- and bidirectional transfers)*			

* e.g. interlaboratory comparisons, use of spiked samples and/or reference materials of known concentration if available.

[4] For qualitative methods with a quantitative component: repeatability tests may however be useful to assess the random error.

5. Number of samples to be analysed

The number of analysed samples must be adapted according to the statistical interpretation that is made.

A reduced number of tests must be justified according to relevant criteria (rarity of the matrix, analysis costs, duration of analysis, etc.) and taken into account in the calculations and tests used.

For information, some guides referenced in the annex provide indications as to the number of samples to be analysed.

6. Methods validated by an independent body

The laboratory may use methods validated according to the requirements of the ISO 16140-2 standard or an equivalent protocol by an independent body (if possible accredited).

These methods are thus categorised as standard methods with regard to the requirements of the ISO/IEC 17025 standard.

7. CE marking

The directive 98/79/CE of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices is transposed by the modified Grand-Ducal Regulation of the 24th July 2001 on medical devices.

Thus, medical laboratories shall use equipments and reagents that have the required CE marking, whenever such equipments and reagents are available.

If, for specific needs, there are no CE-IVD marked medical devices on the market, laboratories may use other devices, provided that they carry out complete validation of the method.

8. Annexes:

8.1 Definitions

A set of definitions on the topic is given below:

Residual risk

Risk remaining after risk control measures have been taken.

(ISO/CEI Guide 51:2014)

Measurement repeatability

Measurement precision under a set of repeatability conditions of measurement (JCGM 200 (VIM): 2012).

Repeatability condition of measurement

Condition of measurement, out of a set of conditions that includes the same measurement procedure, same operators, same measuring system, same operating conditions and same location, and replicate measurements on the same or similar objects over a short period of time.

NOTE 1 A condition of measurement is a repeatability condition only with respect to a specified set of repeatability conditions.

NOTE 2 In chemistry, the term “intra-serial precision condition of measurement” is sometimes used to designate this concept.

(JCGM (VIM): 2012)

Measurement reproducibility

Measurement precision under reproducibility conditions of measurement.

NOTE Relevant statistical terms are given in ISO 5725-1:1994 and ISO 5725-2:1994.

(JCGM 200 (VIM):2012)

Reproducibility condition of measurement

Condition of measurement, out of a set of conditions that includes different locations, operators, measuring systems, and replicate measurements on the same or similar objects.

NOTE 1 The different measuring systems may use different measurement procedures.

NOTE 2 A specification should give the conditions changed and unchanged, to the extent practical.

(JCGM 200 (VIM):2012)

Intermediate measurement precision

Measurement precision under a set of intermediate precision conditions of measurement.

NOTE Relevant statistical terms are given in ISO 5725-3:1994.

(JCGM (VIM): 2012)

Intermediate precision condition of measurement

Condition of measurement, out of a set of conditions that includes the same measurement procedure, same location, and replicate measurements on the same or similar objects over an extended period of time, but may include other conditions involving change.

NOTE 1 The changes can include new calibrations, calibrators, operators, and measuring systems.

NOTE 2 A specification for the conditions should contain the conditions changed and unchanged, to the extent practical.

NOTE 3 In chemistry, the term “inter-serial precision condition of measurement” is sometimes used to designate this concept.

(JCGM (VIM): 2012)

Diagnostic sensitivity

Ability of an in vitro diagnostic examination procedure to identify the presence of a target marker associated with a particular disease or condition.

(ISO 18113-1:2009)

Diagnostic specificity

Ability of an in vitro diagnostic examination procedure to recognise the absence of a target marker associated with a particular disease or condition.

(ISO 18113-1:2009)

Measurement trueness

Closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value.

NOTE 1 Measurement trueness is not a quantity and thus cannot be expressed numerically, but measures for closeness of agreement are given in ISO 5725.

NOTE 2 Measurement trueness is inversely related to systematic measurement error, but is not related to random measurement error.

NOTE 3 "Measurement accuracy" should not be used for 'measurement trueness'.

(JCGM 200 (VIM): 2012)

Measurement accuracy

Closeness of agreement between a measured quantity value and a true quantity value of a measurand.

NOTE 1 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.

NOTE 2 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.

NOTE 3 'Measurement accuracy' is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measurand.

(JCGM (VIM): 2012)

Measurement uncertainty

Non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used.

NOTE 1 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.

NOTE 2 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.

NOTE 3 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.

NOTE 4 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.

(JCGM (VIM): 2012)

Reference interval

Specified interval of the distribution of values taken from a biological reference population.

EXAMPLE The central 95 % biological reference interval for sodium ion concentration values in serum from a population of presumed healthy male and female adults is 135 mmol/l to 145 mmol/l.

NOTE 1 A reference interval is commonly defined as the central 95 % interval. Another size or an asymmetrical location of the reference interval could be more appropriate in particular cases.

NOTE 2 A reference interval can depend upon the type of primary samples and the examination procedure used.

NOTE 3 In some cases, only one biological reference limit is important, for example, an upper limit, x, so that the corresponding biological reference interval would be less than or equal to x.

NOTE 4 Terms such as 'normal range', 'normal values', and 'clinical range' are ambiguous and therefore discouraged.

(ISO 15189:2012)

Decision threshold

Value of the estimator of the measurand, which when exceeded by the result of an actual measurement using a given measurement procedure of a measurand quantifying a physical effect, one decides that the physical effect is present.

(ISO 11929:2010)

Detection limit

Measured quantity value, obtained by a given measurement procedure, for which the probability of falsely claiming the absence of a component in a material is β, given a probability α of falsely claiming its presence.

NOTE 1 IUPAC recommends default values for α and β equal to 0.05.

NOTE 2 The abbreviation LOD is sometimes used.

NOTE 3 The term "sensitivity" is discouraged for 'detection limit'.

(JCGM (VIM): 2012)

Limit of quantification

The smallest amount or concentration of an analyte in the test sample which can be determined with a fixed precision.

(ISO 11885:2007)

Linearity

Ability of a method of analysis, within a certain range, to provide an instrumental response or results proportional to the quantity of analyte to be determined in the laboratory sample.

(ISO 16577:2016)

Analytical recovery

Ratio of the mass of analyte measured in a sample to the known mass of analyte in that sample.

NOTE: The analytical recovery is usually given as a percentage.

EN 1540:2011

Analytical specificity

Capability of a measuring system, using a specified measurement procedure, to provide measurement results for one or more measurands which do not depend on each other nor on any other quantity in the system undergoing measurement.

(ISO 18113-1:2009)

Analytical interference

Systematic effect on a measurement caused by an influence quantity, which does not by itself produce a signal in the measuring system, but which causes an enhancement or depression of the value indicated.

(ISO 18113-1:2009)

Ruggedness

Measure of the capacity of an analytical procedure to remain unaffected by small variations in method parameters and provides an indication of the method's reliability during normal usage.

(ISO 16577:2016)

Measurement principle

Phenomenon serving as a basis of a measurement.

EXAMPLE 1 Thermoelectric effect applied to the measurement of temperature.

EXAMPLE 2 Energy absorption applied to the measurement of amount-of-substance concentration.

EXAMPLE 3 Lowering of the concentration of glucose in blood in a fasting rabbit applied to the measurement of insulin concentration in a preparation.

NOTE The phenomenon can be of a physical, chemical, or biological nature.

(JCGM (VIM): 2012)

Measurement method

Generic description of a logical organization of operations used in a measurement.

NOTE

Measurement methods may be qualified in various ways such as:

— substitution measurement method,

— differential measurement method, and

— null measurement method;

or

— direct measurement method, and

— indirect measurement method.

(JCGM (VIM): 2012)

Verification

Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

NOTE 1 The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

NOTE 2 The activities carried out for verification are sometimes called a qualification process.

NOTE 3 The word "verified" is used to designate the corresponding status.

(ISO 9000:2015)

Validation

Confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled.

NOTE 1 The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

NOTE 2 The word "validated" is used to designate the corresponding status.

NOTE 3 The use conditions for validation can be real or simulated.

(ISO 9000:2015)

8.2 References and bibliography

Number of samples to be analysed

1. ISO 16140-2:2016: Microbiology of the food chain -- Method validation -- Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method.
2. Guide technique d'accréditation de vérification (portée A)/ validation (portée B) des méthodes de biologie médicale: COFRAC (Comité Français d'Accréditation) SH GTA04.
3. Validierung / Verifizierung von Methoden in der Virologie: Gesellschaft für Virologie e.V., Muster VA aus dem Institut für Medizinische Virologie Universitätsklinikum Frankfurt.

Standards and guidelines

4. ISO 16140-2:2016: Microbiology of the food chain -- Method validation -- Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method.
5. The Fitness for Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics: Eurachem, Second edition (2014).
6. Guide technique d'accréditation de vérification (portée A)/ validation (portée B) des méthodes de biologie médicale: COFRAC (Comité Français d'Accréditation) SH GTA04.
7. Richtlinie der Bundesärztekammer zur Qualitätssicherung laboratoriumsmedizinischer Untersuchungen – Rili-BÄK. Deutsches Ärzteblatt, Jg. 111, Heft 38, 19. September 2014, A 1583.
8. Validierung / Verifizierung von Methoden in der Virologie : Gesellschaft für Virologie e.V., Muster VA aus dem Institut für Medizinische Virologie Universitätsklinikum Frankfurt.
9. Guide pour la validation des méthodes d'essais chimico-physiques et l'évaluation de l'incertitude de mesure: SAS (Schweizerische Akkreditierungstelle) doc. n°324.
10. Validierung und Verifizierung von Prüfverfahren nach den Anforderungen der DIN EN ISO/IEC 17025 für Prüflaboratorien auf dem Gebiet der chemischen und chemisch-physikalischen Analytik im Bereich der Abteilung 4 (Gesundheitlicher Verbraucherschutz | Agrarsektor | Chemie | Umwelt) : DAkkS (Deutsche Akkreditierungsstelle) 71 SD 4 019.
11. Leitfaden des Sektorkomitees Pathologie/Neuropathologie für die Validierung von Untersuchungsverfahren in der Immunhistologie : DAkkS (Deutsche Akkreditierungsstelle) 71 SD 4 028.
12. Guide Technique d'Accréditation - Analyses des radionucléides dans l'environnement, dans les produits d'origine animale et les denrées alimentaires destinées à l'homme ou aux animaux : COFRAC (Comité Français d'Accréditation) LAB GTA35.
13. Comité Qualité de la Société Française de Microbiologie (QUAMIC) 2016 v1 : Société Française de Microbiologie.
14. ENV ISO 13843: Water quality – Guidance on validation of microbiological methods (ISO/TR 13843:2000).
15. ISO 11352: 2012 Water quality – Estimation of measurement uncertainty based on validation and quality control data.
16. NF T90-210:2009: Qualité de l'eau - Protocole d'évaluation initiale des performances d'une méthode dans un laboratoire (AFNOR).
17. ISO 3534-1:2006: Statistics – Vocabulary and symbols -- Part 1: General statistical terms and terms used in probability.
18. ISO 5725: Accuracy (trueness and precision) of measurement methods and results Part-1:1994: General principles and definitions,

Part-2:1994: Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method,
Part-3:1994: Part 3: Intermediate measures of the precision of a standard measurement method,
Part-4:1994: Part 4: Basic methods for the determination of the trueness of a standard measurement method.

19. ISO 13528:2015: Statistical methods for use in proficiency testing by interlaboratory comparison.
20. ISO/TS 13530:2009: Water quality – Guidance on analytical quality control for chemical and physicochemical water analysis.
21. ANSES/PR3/7/07: octobre 2015 : Guide de validation des méthodes d'analyses (ANSES)
22. NF V 03 110:2010 : Analyses des produits agricoles et alimentaires – protocole de caractérisation en vue de la validation d'une méthode d'analyse quantitative par construction du profil d'exactitude (AFNOR)
23. NF V 03 111:1995: Analyses des produits agricoles et alimentaires – protocole d'évaluation intra-laboratoire d'une méthode d'analyse qualitative par rapport à une méthode de référence (AFNOR).
24. Trapadoux F. (October 2013). *La validation des méthodes en biologie médicale* [Présentation PowerPoint] Training given at the "Journée de la Communauté de l'Accréditation".
25. Trouvé R. (October 2013). *Validation des méthodes qualitatives* [Présentation PowerPoint] Training given at the "Journée de la Communauté de l'Accréditation".
26. EURAMET Calibration Guides and Technical Guides (https://www.euramet.org/publications-media-centre/cgs-and-tgs/)
27. Guides of the International Organization of Legal Metrology (https://www.oiml.org/fr/publications/guides/)

Accreditation standards

28. ISO/CEI 17025:2017: General requirements for the competence of testing and calibration laboratories.
29. ISO 15189:2012: Medical laboratories – Requirements for quality and competence.

Definitions

30. International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM, 3rd edition) JCGM 200:2012 (JCGM 200:2008 with minor corrections)
31. ISO 18113-1:2009: In vitro diagnostic medical devices -- Information supplied by the manufacturer (labelling) -- Part 1: Terms, definitions and general requirements.
32. ISO/IEC Guide 51:2014: Safety aspects -- Guidelines for their inclusion in standards.
33. ISO 11929:2010: Determination of the characteristic limits (decision threshold, detection limit and limits of the confidence interval) for measurements of ionizing radiation -- Fundamentals and application.
34. ISO 11885:2007: Water quality -- Determination of selected elements by inductively coupled plasma optical emission spectrometry (ICP-OES).
35. ISO 16577:2016: Molecular biomarker analysis -- Terms and definitions.
36. EN 1540:2011: Workplace exposure. Terminology.