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10. Vocabulary for Describing the Metrological Quality of a Measurement Procedure

With an alphabetic index

René Dybkær

Department of Clinical Chemistry Frederiksberg Hospital, Frederiksberg, Danmark

Laboratory medicine is characteristic in having practitioners with various educational backgrounds. Current terms have therefore not been chosen according to a systematic plan and seldomly with adequate knowledge of modern metrological and statistical terminology work.

The following vocabulary comprises sections of salient concepts related to quality, metrology, statistics, metrological performance characteristics, and reference measurement systems. When a definition is given with a reference in brackets, the sign "=" indicates that the definition is taken *verbatim*, the sign "≈" shows that editorial differences have been introduced for consistency, and no sign means that the reference is a source in general.

If no reference is given, the definition is materially different from the set of references given att the end of the vocabulary.

The notes are not necessarily taken directly from any source of the definition - unless followed by a reference in [ ], which then also applies to the definition unless it has a reference already.

It should be emphasized that definitions of concepts and their terms are continuously being developed and changed so that it is always useful to consult the latest editions of relevant documents from standards bodies. The terminological evolution also means that disagreement may exist between the standards or recommendations from different organizations and even from different committees within a given body.

The present selection has taken the International vocabulary of basic and general terms in metrology (see BIPM *et al.*) as the highest authority, followed by ISO, CEN, and professional international unions.

1 QUALITY

WHO - HEALTH for All by the Year 2000

Ensuring the quality of services

Target 31

By 1990, all member states should have built effective mechanisms for ensuring quality of patient care within their health care systems.

1.1 quality

totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs

[= ISO 8402:1986]

1.2 quality policy

overall quality intentions and directions of an organization as regards quality, as formally expressed by top management

[= ISO 8402:1986]

1.3 quality management

that aspect of the overall management function that determines and implements the quality policy

Notes

1. The attainment of desired quality requires the commitment and participation of all members of the organization whereas the responsibility for quality management belongs to top management.
2. Quality management includes strategic planning, allocation of resources and other systematic activities for quality such as quality planning, operations and evaluations.

[= ISO 8402:1986]

1.4 quality system

organizational structure, responsibilities, processes, and resources for implementing quality management

[= ISO 8402:1986]

1.5 quality assurance

all those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality

[= ISO 8402:1986]

1.6 quality control

operational techniques and activities that are used to fulfil requirements for quality

[= ISO 8402:1986]

Notes

1. In order to avoid confusion, care should be taken to include a modifying term when referring to a subset of quality control.
2. Quality control involves operational techniques and activities aimed both at monitoring a process and at eliminating causes of unsatisfactory performance.

1.7 quality audit

systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives

[= ISO 8402:1986]

Notes

1. Quality audits are carried out by independent staff.
2. One purpose of a quality audit is to evaluate the need for improvement or corrective action. The concept should not be confused with "surveillance" or "inspection" performed for the sole purpose of process control or product acceptance.

2 MEASURABLE QUANTITY

2.1 system

demarcated part of the perceivable or conceivable universe, material or immaterial, that may be regarded as a set of elements and a set of relationships between these elements, and that may be observed at a given calendar time

Note

This concept is allied to "object", *i.e.* any part of the perceivable or conceivable world [ISO 1087:1990].

2.2 set

well-defined finite or infinite collection of elements

Note

The elements may be physical objects, numbers, concepts, or sets.

2.3 measurable quantity

quantity

attribute of a phenomenon, body or substance that may be distinguished qualitatively and determined quantitatively

[= VIM, 1993]

2.4 component

definable part of a system

Notes

1. Components can be mechanical, physical, chemical, mathematical, or functional.
2. Components are sometimes divided in analyte, concomitant(s), and solvent.

2.5 elementary entity

relevant structure of a chemical component such as an atom, molecule, ion, electron, other particle, or specified group of such particles

Note

The elementary entity may be chosen as convenient, not necessarily as physically real, individual particles, for example 0,5 Ca^{2+}.

2.6 kind-of-quantity

quantity in a general sense

definition of how to obtain a value of a quantity by measuring a quantity of its system or of its components or both

Examples

length; volume; amount-of-substance; mass concentration; volume fraction

Note

This concept is called "quantity in a general sense" by VIM.

2.7 generic quantity

description of an attribute of a generic system

Note

A generic system is a system lacking specification of space or calendar time or both.

2.8 value of a measurable quantity

value

x, y

magnitude of a measurable quantity generally expressed as a unit of measurement multiplied by a number

Note

A measurable quantity that cannot be expressed as a unit of measurement multiplied by a number may be expressed by reference to a conventional reference scale or to a measurement procedure or to both.

[≈ VIM, 1993]

2.9 unit of measurement

unit

measurable quantity, defined and adopted by convention, with which other measurable quantities of the same kind are compared in order to express their magnitudes relative to that quantity

[≈ VIM, 1993]

2.10 numerical value of a measurable quantity

numerical value

number by which the unit of measurement is multiplied in the expression of the value of a measurable quantity

[≈ VIM, 1993]

2.11 truth

<metrology> quality of being in accordance with the definition of a measurable quantity that may be represented by a distribution of true values

2.12 true value of a measurable quantity

true value

μ

value consistent with the definition of a given measurable quantity

[≈ VIM, 1993]

2.13 conventional true value of a measurable quantity

conventional true value

$\hat{\mu}$

value attributed to a measurable quantity and accepted, sometimes by convention, as having an uncertainty of measurement appropriate for a given purpose

[≈ VIM, 1993]

Note

Quasi-synonyms are "assigned value", "best estimate of the value", "accepted reference value".

3 METROLOGY

3.1 metrology

science of measurement

Note

Metrology includes all aspects both theoretical and practical with reference to measurements, whatever their uncertainty, and in whatever fields of science or technology they occur.

[= VIM, 1993]

3.2 measurement

set of operations having the object of determining a value of a quantity

Note

The operations may be performed automatically.

[= VIM, 1993]

3.3 principle of measurement

scientific basis of a measurement

[= VIM, 1993]

3.4 method of measurement

logical sequence of operations, described generically, used in the performance of measurements

[= VIM, 1993]

3.5 measurement procedure

set of operations, described specifically, used in the performance of particular measurements according to a given method

[= VIM, 1993]

3.6 measurand

measurable quantity subject to measurement

Note

A specification of a measurand may require statements about quantities such as time, temperature and pressure.

[≈ VIM, 1993]

3.7 measuring instrument

device intended to be used to make measurements, alone or in conjunction with supplementary device(s)

[= VIM, 1993]

3.8 measuring system

complete set of measuring instruments and other equipment assembled to carry out specified measurements

[= VIM, 1993]

Note

A measuring system may include materials, such as chemical or biological substances and material measures.

3.9 indication of a measuring system

indication

value of a measurable quantity provided by a measuring system

Notes

1. The value read from the displaying device may be called the "direct indication"; it is multiplied by the instrument constant to give the indication.
2. The measurable quantity may be the measurand, a measurement signal, or another quantity to be used in calculating the value of the measurand.

[≈ VIM, 1993]

3.10 input measurable quantity

input quantity

X_g

measurable quantity whose value is used in calculating a value for the output measurable quantity according to a function

Examples

indication of the measuring system; quantity represented by a calibrator; any influence quantity

Notes

1. All input quantities may be regarded as random variables.
2. The measurand can be considered an output quantity.

3.11 observed value of a measurable quantity

observed value

value of a measurable quantity obtained as the outcome of a single observation

Note

One or more observed values of each input measurable quantity may be needed and may have to be corrected before applying a specified function to obtain a result of a measurement.

3.12 result of a measurement

result

y

value attributed to a measurand, obtained by measurement

[= VIM, 1993]

Notes

1. When a result is given, it should be made clear whether it refers to
   - the indication
   - the uncorrected result
   - the corrected result

   and whether several values are averaged.
2. A complete statement of the result of a measurement includes information about the uncertainty of measurement.

[= VIM, 1993]

3.13 sampling

process of taking samples, usually qualified by a description of the sampling procedure

[≈ ISO/DIS 3534-2:1986]

3.14 sample

one or more parts taken from a system and intended to provide information on the system or to serve as a basis for a decision on the system

Notes

1. Unless otherwise specified, the sample is assumed to be representative of a "static system".
2. The system from which a sample is taken may not be of the same type as that of the measurand.
3. For a "dynamic system", the calendar time of sampling has to be specified.

3.15 primary sample

collection of one or more parts initially taken from a system

[≈ IUPAC, 1990]

3.16 laboratory sample

primary sample or a subsample of it as prepared for sending to or as received by the laboratory and intended for measurement

Note

The laboratory sample is the final sample of sample collection and the initial sample in the laboratory.

3.17 analytical sample

sample prepared from the laboratory sample and from which analytical portions may be taken

3.18 analytical portion

portion of material taken from the analytical sample and on which the measurement of an appropriate measurable quantity is actually carried out

3.19 analytical run

analytical series

set of measurements performed under repeatability conditions

4 STATISTICS

4.1 probability

real number in the scale of 0 to 1 attached to a random event

[= ISO/DIS 3534-1:1990]

Note

Probability can be related to a long-run number fraction of occurrence or to a degree of belief that an event will occur. For a high degree of belief, the probability is near 1.

4.2 random variable

variate

X, Y

variable that may take any of the values of a specified set of values and with which is associated a probability distribution

[= ISO/DIS 3534-1:1990]

4.3 probability distribution of a random variable

probability distribution

function that gives the probability that a random variable takes any given value or belongs to a given set of values

Note

The probability on the whole set of values of the random variable equals 1.

[= ISO/DIS 3534-1:1990]

4.4 location

<statistics> typical magnitude of a distribution of values

Examples

arithmetic mean; median; mode

4.5 dispersion

<statistics> degree of scatter shown by a set of values

Examples

standard deviation; central 0,95-interfractile interval

4.6 population

totality of items under consideration

[= ISO/DIS 3534-1:1990]

Note

In the case of a random variable, the probability distribution is considered as defining the population of that variable.

4.7 population parameter

parameter

quantity used in describing the distribution of a random variable in a population

[= ISO/DIS 3534-1:1990]

4.8 expectation of a random variable

expectation

$E(X)$, $E(Y)$

expected value

mean

sum of products of values x_j of a discrete random variable X and their respective probabilities p_j, the sum being extended over all values x_j that can be taken by X

$E(X) = \Sigma\, p_j x_j$

4.9 variance of a random variable

variance of a probability distribution

variance

σ^2_x, $V(X)$, $V(Y)$

expectation of the square of the centred random variable

$\sigma^2_x = E\{[X - E(X)]^2\}$

[= ISO/DIS 3534-1:1990]

4.10 standard deviation of a random variable

standard deviation of a probability distribution

standard deviation

σ

positive square root of the variance of a random variable

$\sigma_x = \sqrt{V(X)}$, $\sigma_y = \sqrt{V(Y)}$

[≈ ISO/DIS 3534-1:1990]

4.11 coefficient of variation of a random variable

coefficient of variation of a probability distribution

coefficient of variation

$\sigma/E(X)$, σ/μ

ratio of the standard deviation to the expectation of a non-negative random variable

$\sigma/\mu = \sqrt{V(X)}\,/E(X)$

[= ISO/DIS 3534-1:1990]

DO NOT USE: relative standard deviation (deprecated)

4.12 statistic

function of the sample random variables

[= ISO/DIS 3534-1:1990]

Notes

1. The value of the statistic obtained by using the observed values or results of measurements in this function may be used in a statistical test or as an estimate of a population parameter such as an expectation of a random variable or a standard deviation of a random variable.
2. A statistic is itself a random variable.

4.13 estimator

statistic used to estimate a population parameter

[= ISO/DIS 3534-1:1990]

4.14 estimate, noun

value of an estimator obtained as a result of an estimation

[= ISO/DIS 3534-1:1990]

4.15 number fraction distribution

relative frequency distribution

empirical relationship between the values of a random variable and their number fractions

Note

The term "frequency distribution" is often used for the different concepts "number distribution" and "number fraction distribution".

4.16 arithmetic mean

average

$\bar{x}$, $\bar{y}$

sum of values divided by the number of values

[= ISO/DIS 3534-1:1990]

Note

The term "mean" or "expectation" should be used only for the population parameter.

4.17 median

with n values arranged in non-decreasing order of magnitude 1 to n, the $((n + 1)/2)$th value of n odd values or a value between $(n/2)$th and $(n/2 + 1)$th even values with the arithmetic mean of these values chosen if not otherwise specified

[≈ ISO/DIS 3534-1:1990]

Note

An alternative definition is: 0,5-fractile.

4.18 sample variance

s^2

sum of the squared deviations of results of measurements from their arithmetic mean divided by one less than the number of results

$$s^2 = \frac{1}{n-1} \Sigma (x_j - \bar{x})^2$$

Note

The sample variance is an unbiased estimator of the population variance

[≈ ISO/DIS 3534-1:1990]

4.19 fractile of a random variable

fractile

x_p

variate value equal to or below which lies a stated number fraction of the cumulative number fraction distribution

4.20 confidence interval

closed interval within which the value of a population parameter may be expected to lie with a stated probability

Note

This approximate definition is valid for a two-sided confidence interval.

4.21 statistical coverage interval

interval for which it can be stated with a given level of confidence that it contains at least a specified proportion of the population

[= ISO/DIS 3534-1:1990]

4.22 tolerance interval

variate values between and including the tolerance limits giving upper and lower limits to permissible values

4.23 statistical outlier

outlier

observed value in a sample, so far separated in value from the remainder as to suggest that it may be from a different population

[≈ ISO/DIS 3534-1:1990]

5 ERROR

5.1 error of a result of a measurement

error of measurement

error

result of a measurement minus a true value of the measurand

[= VIM, 1993]

Notes

1. Since a true value cannot be determined, in practice, a conventional true value is used [= VIM, 1993].
2. Error is the sum of random error and systematic error [ISO/DIS 3534-1:1990].
3. If several components of error are listed, "error" may be named "total error".

5.2 deviation

value minus its reference value

[= VIM, draft 2. ed.]

5.3 random error of a result of a measurement

random error

e

result of a measurement minus the mean that would result from an infinite number of measurements of the same measurand carried out under repeatability conditious

$e = y - E(Y_{i,r})$

[= VIM, 1993]

Notes

1. Since the mean is not known, in practice, the arithmetic mean is usually substituted.

2. It is not possible to correct for random error as it varies unpredictably in successive results.

5.4 systematic error of a result of a measurement

systematic error

mean that would result from an infinite number of measurements of the same measurand carried out under repeatability conditions minus a true value of the measurand

[= VIM, 1993]

Notes

1. Since the mean (or expectation) is not known, in practice, the arithmetic mean is usually substituted.
2. Since a true value cannot be determined, in practice, a conventional true value is used.
3. The systematic error of successive results remains constant or varies in a predictable way.

5.5 correction

value added algebraically to the uncorrected result of a measurement to compensate for systematic error

[= VIM, 1993]

Notes

1. The correction is equal to the negative of the estimated systematic error.
2. Some systematic errors may be estimated, and compensated by applying appropriate corrections. However, since the systematic error cannot be known perfectly, the compensation cannot be complete.

5.6 correction factor

numerical factor by which the uncorrected result of a measurement is multiplied to compensate for systematic error

[= VIM, 1993]

Note

Since the systematic error cannot be known perfectly, the compensation cannot be complete.

[= VIM, 1993]

5.7 mistake

blunder

unauthorized departure from the prescribed measurement procedure

Note

The mistake can take the form of an omission or an incorrect action. This is to be distinguished from "error of measurement".

6 ACCURACY

6.1 accuracy of measurement

accuracy

closeness of the agreement between the result of a measurement and a true value of the measurand

[= VIM, 1993]

DO NOT USE: precision (deprecated)

Notes

1. Accuracy of measurement can be measured on an ordinal scale such as (poor, fair, good).
2. Accuracy is usually expressed numerically by statistical measures of the inverse concept "inaccuracy of measurement".
3. The term "accuracy", when applied to a set of results, describes a combination of "random error of measurement" and "systematic error of measurement".

6.2 trueness of measurement

trueness

closeness of the agreement between the average value obtained from a large run of results of measurements and a true value

Notes

1. Trueness of measurement can be measured on an ordinal scale such as (low, medium, high).
2. Trueness is usually expressed numerically by the statistical measure "bias" that is inversely related to trueness.

6.3 bias of measurements

bias

difference between the expectation of the results of measurements and a true value

DO NOT USE: inaccuracy

Notes

1. Bias is a "systematic error of results of measurements" and it may have several components.
2. Since a true value cannot be determined, in practice, a "conventional true value" is used.

6.4 precision of measurements

precision

closeness of the agreement between independent results of measurements obtained under prescribed conditions

[≈ ISO/DIS 3534-1:1990]

Notes

1. Precision of measurements can be measured on an ordinal scale such as (low, medium, high).
2. Precision is usually expressed numerically by statistical measures of the inverse concept "imprecision of measurements".
3. Precision depends only on the distribution of "random errors of measurement".

6.5 precision conditions

statement of conditions of measurement under which independent results of measurements of the same measurand are obtained, specifying which sources of variation operate

Note

The term "independent results" means that a given result must not be influenced by any previous result.

7 COMPONENTS OF A RESULT

7.1 overall expectation of results of measurements

overall expectation

E(Y), m

expectation of results of measurements of a given measurand as obtained from all

laboratories using the same measurement procedure in a collaborative assessment experiment

Note

The overall expectation is the sum of a true value of the measurand and the bias of the measurement procedure, $E(Y) = \mu + \delta$, that is the overall expectation depends solely on a true value and the measurement procedure. In some cases, however, an independent true value does not exist and the overall expectation is exclusively defined by the measurement procedure.

7.2 bias of results of a measurement procedure

bias of a measurement procedure

difference between the expectation of all results of measurements made by a stated measurement procedure and a true value of a given measurand to be expected to apply to all measurements made by that procedure

$\delta = E(Y) - \mu = m - \mu$

Notes

1. The bias of a measurement procedure may depend on the value of the measurand.
2. An estimator of this bias is the difference between the general average and a conventional true value, $d = \bar{\bar{y}} - \hat{\mu}$.

7.3 laboratory deviation

B

difference between the expectation of the results of measurements of a laboratory for a given measurand obtained under stated precision conditions and the overall expectation of results of measurements

Notes

1. The laboratory deviation may depend on the value of the measurand.
2. An estimator of this deviation is the difference between the average in the laboratory and the general average of results of measurements, $\hat{B} = \bar{y}_i - \bar{\bar{y}}$
3. The laboratory deviation is given specific names for typical precision conditions.

7.4 laboratory bias of results of a measurement procedure

laboratory bias

Δ

difference between the expectation of all results of measurements made in a given

laboratory using a specified measurement procedure and a true value of the measurand

$\Delta = E(Y_i) - \mu$

Notes

1. The laboratory bias may depend on the value of the measurand.
2. An estimator of this bias is the difference between the average of all results obtained by a given laboratory and a conventional true value,
   $\hat{\Delta} = \bar{y}_i - \hat{\mu}$.

7.5 aberrant-sample bias of the result of measurement

aberrant-sample bias

S

difference between the expectation of the results of measurements on a given sample of unusual composition and the expectation for a measurand of the same magnitude pertaining to a sample having a usual composition

7.6 bias caused by an undetected mistake

M

difference between the result of a measurement on a given sample in a given run and the expectation of repeated results of the same measurand, in excess of any random error

8 REPEATABILITY (see also 7)

8.1 repeatability conditions

conditions of measurement where independent results of measurements of the same measurand are obtained with the same measurement procedure in the same laboratory by the same observer using the same equipment, used under the same conditions within a short period of time

Note

The term "independent results" means that a given result must not be influenced by any previous result.

8.2 laboratory component of bias of results of a measurement procedure

laboratory component of bias

$B_{i,r}$

difference between the laboratory bias of results of a measurement procedure and the bias of results of a measurement procedure

$B_{i,r} = \Delta_{i,r} - \delta = E(Y_i|r) - E(Y) = E(Y_i|r) - m$

Notes

1. The laboratory component of bias is related to the expectation of results of measurements, $E(Y) = m$, not to a true value.
2. The laboratory component of bias is considered constant under repeatability conditions, r, in one laboratory for one measurand, but its value may depend on the value of the measurand.
3. An estimator of this bias is the difference between the average of all results of measurements obtained by a given laboratory and the general average, $B_{i,r} = \Delta_{i,r} - d = \bar{y}_{i,r} - \hat{m} = \bar{y}_{i,r} - \bar{\bar{y}}$.

8.3 repeatability of results of measurements

repeatability

closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement

Notes

1. Repeatability conditions (see 8.1) include:
   - the same measurement procedure,
   - the same observer,
   - the same measuring instrument, used under the same conditions,
   - the same location,
   - repetition over a short period of time
2. Repeatability depends solely on the dispersion of random error and does not relate to a true value.
3. Repeatability can be measured on an ordinal scale of measurement such as (poor, good, excellent).

[= VIM, 1993]

8.4 within-laboratory repeatability variance of results of measurements

within-laboratory repeatability variance

$\sigma^2_{i,r}$, σ^2_w

variance of the distribution of random errors within a single laboratory under repeatability conditions

Notes

1. An alternative definition, which includes the dispersion of true values is: variance of the distribution of results of measurements within a single laboratory under repeatability conditions.
2. The value may depend on the value of the measurand.
3. An estimator of σ^2_w is the sample within-laboratory repeatability variance, s^2_w.

8.5 repeatability variance of results of measurements

repeatability variance

σ^2_r

average of the within-laboratory repeatability variances of results of measurements taken over all the laboratories using a given measurement procedure in a precision experiment

$\sigma^2_r = \overline{\sigma^2_w}$

Notes

1. It is assumed that for a given measurement procedure any variation in the variances between the laboratories is small.
2. The value of the repeatability variance may depend on the value of the measurand.
3. An estimator of σ^2_r is the sample repeatability variance, s^2_r.

9 INTERMEDIATE PRECISION (see also 7)

9.1 intermediate precision conditions

conditions of measurement where independent results of measurement of the same measurand are obtained with the same measurement procedure in the same laboratory subject to stated changes in one or more sources of variation such as time, observer, and measuring system

Note

The term "independent results" means that a given result must not be influenced by any previous result.

9.2 intermediate precision of results of measurements

intermediate precision

closeness of agreement between the results of measurements of the same measurand, where the measurements are carried out in the same laboratory by the same measurement procedure, but with stated changes in one or more sources of variation such as time, observer, and measuring system

Notes

1. Results are here usually understood to be corrected results.
2. The Notes 1, 2, and 3 to precision of measurements apply analogously.

10 REPRODUCIBILITY (see also 7)

10.1 reproducibility conditions

conditions of measurement where independent results of measurement of the same measurand are obtained with the same measurement procedure in different laboratories with different observers using different equipment

Notes

1. The term "independent results" means that a given result must not be influenced by any previous result.
2. The definition in VIM, 1993, allows principle of measurement, methods of measurement, and conditions of use as added possible sources of variation.
3. The conditions changed must always be specified.

10.2 reproducibility of results of measurements

reproducibility

closeness of the agreement between the results of measurements of the same measurand, where the measurements are carried out by the same measurement procedure, but in different laboratories with different observers using different equipment

Notes

1. A valid statement of reproducibility requires specification of the conditions changed.
2. Results are here usually understood to be corrected results.
3. The Notes 1, 2, and 3 to precision of results of measurements apply analogously.
4. The definition in VIM, 1993, allows principle of measurement, method of measurement, and conditions of use as added possible sources of variation.

10.3 between-laboratory variation

B_R

distribution of the individual laboratory-component-of-bias of results of measurements obtained under defined precision conditions.

10.4 between-laboratory variance of results of measurements

between-laboratory variance

$\sigma^2_{B_R} = \sigma^2_L$

variance of the distribution of the laboratory components of bias of results of a measurement procedure obtained under reproducibility conditions

Notes

1. The distribution is assumed to be at least approximately Gaussian.
2. The between-laboratory variance may depend on the value of the measurand.
3. An estimator of σ^2_L is the sample between-laboratory variance, s^2_L.

10.5 reproducibility variance of results of measurements

reproducibility variance

σ^2_R

sum of the repeatability variance of results of measurements and the between-laboratory variance of results of measurements $\sigma^2_R = \sigma^2_r + \sigma^2_L$

Notes

1. The reproducibility variance may depend on the value of the measurand.
2. An estimator of σ^2_R is the sample reproducibility variance, $s^2_R = s^2_r + s^2_L$.

10.6 between-procedure variation

δ_p

distribution of individual bias of results of measurement procedures under defined precision conditions

11 ANALYTICAL RELIABILITY
METROLOGICAL RELIABILITY

11.1 analytical reliability

metrological reliability

ability of a measurement procedure to perform a required function under stated conditions for a stated period of time

[≈ ISO 8402:1986]

11.2 analytical performance characteristic

metrological performance characteristic

performance characteristic

property in the set of properties that is necessary for assessing the suitability of a measurement procedure for any given purpose and where each property can be given an experimentally determined value

Examples

analytical sensitivity; repeatability standard deviation; limit of detection

11.3 analytical calibration function

metrological calibration function

calibration function

signal of the measuring system as a function of the stated value of the measurand

Note

The stated value may be the assigned value of a reference material.

11.4 analytical sensitivity

S_i

slope of the analytical calibration function

Notes

1. The analytical sensitivity may vary with the magnitude of the measurand involving the component *i* or with influence quantities.
2. The term "analytical sensitivity" must not be used as a synonym for "limit of detection".

11.5 analytical measuring function

measuring function

value of the measurand as a function of the signal of the measuring system related to that measurand and derived from the analytical calibration function

Note

The analytical measuring function, in principle, is the inverse of the analytical calibration function, but this relationship may not hold if the measurement procedure is not specific for one analyte or where analytical interference occurs.

11.6 influence quantity

measurable quantity that is not the measurand but that affects the result of measurement

[≈ VIM, 1993]

Example

bilirubin concentration in the measurement of hemoglobin concentration in human blood plasma

11.7 analytical specificity

ability of a measurement procedure to determine solely the measurable quantity it purports to measure

Note

The analytical specificity is usually expressed in terms of the effect of any component of the sample other than the analyte causing an indication of the measuring instrument and thereby introducing an error of measurement.

11.8 analytical interference

systematic error of measurement caused by an analytical interferent

11.9 analytical interferent

influence quantity which does not by itself produce a signal in the measuring system, but which causes an enhancement or depression of its indication

Note

Sone analytical chemists prefer that an analytical interferent can itself produce a signal.

11.10 reagent blank measurement

measurement on a material lacking natural sample

Note

The result of the measurement is used as a correction for that part of the indication caused by the reagent(s).

11.11 matrix blank measurement

measurement on a material containing matrix material, but lacking analyte

Notes

1. If matrix material is unavailable, the measurement may be made on sample material, by a modified procedure omitting a reagent or inactivating the analyte.
2. The result of the measurement is used as a correction for that part of the indication caused by the sample matrix.

11.12 recovery measurement

subtracting of the indication of a measuring instrument obtained by measurement on an analytical sample from the indication of another analytical sample of the same laboratory sample containing an added amount of the analyte and comparing with the added amount.

11.13 repeatability standard deviation

σ_r

standard deviation of results of measurements obtained under repeatability conditions

[≈ ISO/DIS 3534-1:1990]

Notes

1. Synonyms of "repeatability standard deviation" are "within-run standard deviation", "within-series standard deviation", "intra-run standard deviation", and "intra-serial standard deviation".
2. The estimator of "repeatability standard deviation" is the "sample repeatability standard deviation", s_r.

11.14 repeatability limit

r; $r_{0,95}$

value less than or equal to which the absolute difference between two single results of measurements, obtained under repeatability conditions, is expected to be with a probability of 0,95

[≈ ISO/DIS 3534-1:1990]

Note

In practice, the estimate of the repeatability is taken as $2\sqrt{2}\,s_r$ $\approx 2{,}8\,s_r$, see repeatability standard deviation.

11.15 intermediate precision standard deviation

standard deviation of results of measurements obtained under defined intermediate precision conditions

Note

The estimator of "intermediate precision standard deviation" is the "sample intermediate precision standard deviation".

11.16 reproducibility standard deviation

σ_R

standard deviation of results of measurements obtained under reproducibility conditions

[≈ ISO/DIS 3534-1:1990]

Note

The estimator of "reproducibility standard deviation" is the "sample reproducibility standard deviation", s_R.

11.17 reproducibility limit

R; $R_{0,95}$

value less than or equal to which the absolute difference between two single results of measurements, obtained under reproducibility conditions, is expected to be with a probability of 0,95

[≈ ISO/DIS 3534-1:1990]

Note

In practice, the estimate of the reproducibility limit is taken as $2\sqrt{2}\,s_R$ $\approx 2{,}8\,s_R$, see reproducibility standard deviation.

11.18 reproducibility standard deviation divided by analytical sensitivity

σ_R/S_i

11.19 limit of detection

detection limit

lowest result of a measurement by a given measurement procedure that can be accepted

with a stated confidence level as being different from the value obtained on matrix blank material

Note

An experimental procedure for determining the limit of detection consists in using the average value of, say, 20 results of measurements on matrix blank material and adding three times their sample standard deviation. At these low values with probably non-Gaussian distribution, the corresponding confidence level should be taken to be about 0,90.

11.20 lower limit of determination

lowest result of a measurement, that can be obtained by a stated measurement procedure, and that can be given with a statement of uncertainty of measurement.

11.21 higher limit of determination

highest result of a measurement, that can be obtained by a stated measurement procedure, and that can be given with a statement of uncertainty of measurement

11.22 uncertainty of measurement

parameter, associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand

[= VIM, 1993]

Notes

1. The parameter may be, for example, a standard deviation (or a given multiple of it), or the half-width of an interval having a stated level of confidence.
2. Uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated from the statistical distribution of the results of series of measurements and can be characterized by experimental standard deviations. The other components, which can also be characterized by standard deviations, are evaluated from assumed probability distributions based on experience or other information.
3. It is understood that the result of the measurement is the best estimate of the value of the measurand, and that all components of uncertainty, including those arising from systematic effects, such as components associated with corrections and reference standards, contribute to the dispersion.

11.23 robustness of a measurement procedure

robustness

ability to yield acceptable results of measurements in spite of deviation from details of the measurement procedure

11.24 transferability of a measurement procedure

transferability

ability of a measurement procedure to allow observers in different laboratories to perform measurements giving results in accordance with the stated analytical performance characteristics

11.25 interchangeability of a measurement procedure

interchangeability

ability of one measurement procedure to be used in place of another to fulfil the same requirements

[ISO/IEC Guide 2:1986]

11.26 commutability of a measurement procedure

commutability

ability of a measurement procedure to produce results of measurement that, within the uncertainty of measurement, are in a constant relationship with the results of another stated measurement procedure when both are applied to natural samples and reference materials

11.27 compatibility

suitability of products, processes or services for use together under specific conditions to fulfil relevant requirements without causing unacceptable interactions

[= ISO/IEC Guide 2:1986]

12 PRACTICABILITY

12.1 practicability of a measurement procedure

practicability

properties of a measurement procedure concerning number rate of results of measurements, production time of one result, cost, requirements of technical skill, requirements of services and environment, reliability of measuring system, and safety

13 REFERENCE MEASUREMENT SYSTEM

13.1 reference measurement procedure

thoroughly investigated and described measurement procedure having analytical performance characteristics, especially bias and expressions of precision of measurements, permitting its use for assessing the accuracy of other procedures and characterizing reference materials

[ISO Guide 30:1981]

13.2 measurement standard

standard

etalon

material measure, measuring instrument, reference material or measuring system intended to define, realize, conserve or reproduce a unit of measurement or one or more values of a quantity to serve as a reference

[≈ VIM, 1993]

13.3 primary measurement standard

primary standard

measurement standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same [generic] quantity, within a specified context

[≈ VIM, 1993]

13.4 secondary measurement standard

secondary standard

measurement standard whose value is assigned by comparison with a primary standard of the same [generic] quantity

[≈ VIM, 1993]

13.5 reference measurement standard

reference standard

measurement standard generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived

[≈ VIM, 1993]

13.6 working measurement standard

working standard

measurement standard that is used routinely to calibrate or check material measures,

measuring instruments or reference materials

Notes

1. A working standard is usually calibrated against a reference standard.
2. A working standard used routinely to ensure that measurements are being carried out correctly is called a check standard.

[≈ VIM, 1993]

13.7 reference material

RM

material or substance one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement procedure, or for assigning values to materials

[= ISO Guide 30:1992]

13.8 certified reference material

CRM

reference material, accompanied by a certificate, one or more of whose property values are certified by a measurement procedure which establishes traceability to an accurate realization of the measurement unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence

Note

Some reference materials and certified reference materials have properties which, because they cannot be correlated with an established chemical structure or for other reasons, cannot be determined by exactly defined physical and chemical measurement procedures. Such materials include certain biological materials such as vaccines to which an International unit has been assigned by the World Health Organization.

[≈ ISO Guide 30:1992]

13.9 calibration material

calibrator

reference material used for calibration

13.10 control material

material used for the purposes of internal quality control or external quality assessment and subjected to measurement according to the same or part of the same measurement procedure as that used for unknown samples in order to monitor analytical performance

Notes

1. Analyte and matrix should closely resemble those of unknown samples.
2. Control material may or may not meet the requirements of reference materials.

13.11 blank material

material lacking the analyte or another component necessary to produce an indication of a measuring system that is specific to the analyte

Note

Reagent blank material contains no natural sample. Sample blank material contains natural sample, but a modified measurement procedure yields no signal for the analyte.

13.12 calibration

set of operations that establish, under specified conditions, the relationship between values of measurable quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by measurement standards

[≈ VIM, 1993]

13.13 traceability

property of the result of a measurement or the value of a measurement standard whereby it can be related to stated references, usually national or international measurement standards, through an unbroken chain of comparisons having stated uncertainties

[≈ VIM, 1993]

14 ANALYTICAL QUALITY ASSURANCE
METROLOGICAL QUALITY ASSURANCE

14.1 See 1.5

14.2 internal quality control

set of procedures undertaken by the laboratory staff for continuous monitoring of operations and results of measurements in order to decide whether the results are reliable enough to be released and to eliminate causes of unsatisfactory performance

Notes

1. Internal quality control primarily monitors the batchwise trueness of results of

measurements on control materials and precision on replicate measurements of natural samples.

2. Internal quality control in the wider sense applies to all stages of activity in the production of results of measurements from assessing clinical needs, via preparation of the patient, collection of sample, and measurement to reporting of results.

14.3 interlaboratory measurement comparisons

interlaboratory test comparisons

organization, performance and evaluation of measurements on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions

[≈ ISO/IEC Guide 2:1986]

14.4 laboratory proficiency testing

proficiency testing

external quality assessment

system for objectively checking laboratory results of measurements by an external agency, and including comparison of a laboratory's results at intervals with those of other laboratories, the main object being the establishment of trueness

[≈ ISO/REMCO N231:1991]

Note

The main purposes of laboratory proficiency testing are to establish between-laboratory comparability of results and long term stability of analytical performance.

14.5 technical specification

document that prescribes technical requirements to be fulfilled by a product, process or service

Notes

1. A technical specification should indicate, whenever appropriate, the procedure(s) by means of which it may be determined whether the requirements given are fulfilled.
2. A technical specification may be a standard, a part of a standard or independent of a standard.

[= ISO/IEC Guide 2:1986]

14.6 requirement

provision that conveys criteria to be fulfilled

[= ISO/IEC Guide 2:1986]

Note

In a standard, requirements will be indicated by the auxiliary "shall".

14.7 regulation

document providing binding legislative rules, that is adopted by an authority

[= ISO/IEC Guide 2:1986]

15 SCHEMES OF RECOGNITION

15.1 Good Laboratory Practice

GLP

organizational process and the conditions under which laboratory studies are planned, performed, monitored, recorded, and reported

[= OECD:1981]

15.2 certification of conformity

action by a third party, demonstrating that adequate confidence is provided that a duly identified product, process or service is in conformity with a specific standard or other normative document

[= ISO/IEC Guide 2:1986]

15.3 laboratory accreditation

formal recognition that a testing laboratory is competent to carry out specific tests or specific types of tests

Note

The term "laboratory accreditation" may cover the recognition of both the technical competence and the impartiality of a testing laboratory or only its technical competence. Accreditation is normally awarded following successful laboratory assessment and is followed by appropriate surveillance.

[= ISO/IEC Guide 2:1986]

WHO - Health for All by the Year 2000

Health technology assessment

Target 38

Before 1990, all member states should have established a formal mechanism for the systematic assessment of the appropriate use of health technologies and their effectiveness, efficiency, safety and acceptability, while reflecting national health policies and economic restraints.

REFERENCES

Abbreviations of international organizations

BIPM	International Bureau of Weights and Measures
IEC	International Electrotechnical Commission
IFCC	International Federation of Clinical Chemistry
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
IUPAP	International Union of Pure and Applied Physics
OECD	Organization for Economic Co-operation and Development
OIML	International Organization of Legal Metrology

BIPM, IEC, IFCC, ISO, IUPAC, IUPAP, OIML. International vocabulary of basic and general terms in metrology (VIM). 2nd ed. Geneva: ISO, 1993 (in press).

ISO. Terms and definitions used in connection with reference materials. ISO Guide 30, 1st ed. Geneva: ISO, 1981:5 pp.

ISO. Quality - Vocabulary. ISO 8402, 1st ed. Geneva: ISO, 1986:12 pp.

ISO. Statistics - Vocabulary and symbols. Part 2. Statistical quality control. ISO/DIS 3534-2. Geneva: ISO, 1986:iii + 30 pp.

ISO. Statistics - Vocabulary and symbols. Part 1. Probability and general statistical terms. ISO/DIS 3534-1. Geneva: ISO, 1990:80 pp.

ISO. Harmonized proficiency testing protocol. ISO/REMCO N 231, 1991:46 pp.

ISO, IEC. General terms and their definitions concerning standardization and related activities. ISO/IEC Guide 2. Geneva: ISO, 1986:iii + 45 pp.

IUPAC. Nomenclature for sampling in analytical chemistry. Recommendations 1990. Pure Appl Chem 1990;62:1193-1208.

OECD. OECD principles of good laboratory practice. ENV/CHEM/MC/81.14. 1981:15-44.

VIM. See. BIPM et al.

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Correspondence:
René Dybkær
Department of Clinical Chemistry
Frederiksberg Hospital
DK-2000 Frederiksberg, Danmark