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11. Explanation of some other Concepts and Terms Used in this Report

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Analytical procedure

An *analytical procedure* is made up of

1) an *analytical measurement procedure* consisting of the measurement procedure proper, calibration, calculation and correction procedures;
2) an *analytical control procedure.*

This terminology was in principle introduced already in (1) and is preferred here in order to clearly distinguish between the overall procedure and its component parts. Analytical control procedures can be defined by specification of control rule(s), control limits, control material, and the number of control observations.

Different types of variations

Abbreviations:

s_T	total standard deviation (total SD)	CV_T	total coefficient of variation
s_B	total biological SD	CV_B	total biological coefficient of variation. *Etc.*
s_A	total analytical SD		
s_{Bw}	biological within-subject SD		
s_{Bb}	biological between-subject SD		
s_{preA}	pre-analytical SD		
s_{Aw}	analytical within-series SD		
s_{Ab}	analytical between-series SD		
s_{TBw}	total within-subject SD (including biological and analytical variation)		

s_{AwL} analytical within-laboratory SD, can be calculated in different ways, *e.g.* as
i) average for an individual laboratory or
ii) average for several laboratories.

s_{AbL} analytical between-laboratory SD

s_{AL} total analytical SD (including analytical within-lab and between-lab variation)

s_{A0} inherent stable analytical random error (estimated from s_{Aw} or s_{AwL} dependent on problem)

Definitions according to analysis of variation (ANOVA):

$$s_T^2 = s_B^2 + s_A^2 + s_{preA}^2$$
$$s_B^2 = s_{Bw}^2 + s_{Bb}^2$$
$$s_A^2 = s_{Aw}^2 + s_{Ab}^2$$
$$s_{TBw}^2 = s_A^2 + s_{Bw}^2 + s_{preA}^2$$
$$s_{AL}^2 = s_{AbL}^2 + s_{AwL}^2$$

ANOVA is carried out according to references (2, 3).
Similar system for abbreviations of variations have been described by Dot, Miró, and Fuentes-Arderiu (5).

Different types of bias of a measuring instrument

According to Chapter 1 and VIM (4), bias (of a measuring instrument) is defined as a "systematic error of the indication of a measuring instrument". In accordance with ref. (8) we have used bias to describe long term stable systematic errors and ΔSE for short term systematic errors - not included in "averaging the error of indication over an appropriate number of repeated measurements".

Abbreviations:

B_A analytical bias

B_{corr} correctable bias; that part of bias (systematic error), which is well defined and estimated.

$B_{noncorr}$ noncorrectable bias; that part of bias which can not be well estimated.

B_{wL} difference in bias (within a laboratory or for a given instrument) between two time points = $[B_A(t_1) - B_A(t_2)]$.

B_{bL} difference in bias between two laboratories.

B_{bI} difference in bias between two instruments.

The concepts of "analytical stability" and "analytical instability" are introduced in references (8, 9) in order to describe variation in analytical performance over a longer time period expressed as distances between (k; l) points in a two-dimensional co-ordinate system.

Reference interval - reference range

A (biological) reference interval is, if other characteristics are not indicated, defined as a 0.95-interfractile interval (6, 7). The statistical definition of range is "the difference between the highest and the lowest value in a distribution". Reference range is according to this definition the difference between the highest and lowest value in a distribution of reference values.

Errors of a measuring instrument

The total error, TE, is composed of the following terms:

$$TE = Bias_{corr} + Bias_{noncorr} + \Delta SE \cdot s_{A0} + z \cdot \Delta RE \cdot s_{A0}$$

where

ΔSE is a temporary increase of the systematic error, not detected/eliminated by the quality control system of the laboratory. This increase in error is expressed as multiples of s_{A0}. Can have a positive or negative value and be of the order $(0; \Delta SE_{detect})$.

ΔRE is a temporary increase of the random error, not detected/eliminated by the quality control system of the laboratory. The change in random error is expressed as multiples of s_{A0} and is in the order $(0; \Delta RE_{detect})$.

z is a multiplier related to the portion of the distribution exceeding the quality requirement, often set as 1.65 to fix the maximum defect rate to 5 %. Compare ref. (8) (Chapter 5.2).

Quality concepts

Different quality concepts are explained in Chapter 11. We are using both the defined concept "quality assurance" and the concept "quality assessment" with regard to analytical quality *e.g.* in the context of "internal quality assurance" and "external quality assessment and assurance". According to a document produced by ECCLS, "External Quality Assessment" refers to a system of retrospectively and objectively comparing results from different laboratories by means of an external agency. The main object of EQA is to establish the degree of agreement of results, both amongst laboratories and with an absolute standard where one exists" (11). We have used the abbreviation EQAA to represent the type of active "External Quality Assessment and Assurance" program described in ref. 8.

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