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Water quality — Calibration and evaluation of analytical methods and estimation of performance characteristics

Part 1: Statistical evaluation of the linear calibration function

*Qualité de l'eau — Étalonnage et évaluation des méthodes d'analyse et estimation
des caractères de performance*

Partie 1: Évaluation statistique de la fonction linéaire d'étalonnage



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8466-1 was prepared by Technical Committee ISO/TC 147, *Water quality*.

ISO 8466 consists of the following parts, under the general title *Water quality — Calibration and evaluation of analytical methods and estimation of performance characteristics*:

- *Part 1: Statistical evaluation of the linear calibration function*
- *Part 2: Calibration strategy for non-linear calibration functions*
- *Part 3: Method of standard addition*
- *Part 4: Estimation of limit of detection and limit of determination of an analytical basis method.*

Annex A of this part ISO 8466 is for information only.

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Water quality — Calibration and evaluation of analytical methods and estimation of performance characteristics

Part 1: Statistical evaluation of the linear calibration function

1 Scope

This part of ISO 8466 describes the steps to be taken in evaluating the statistical characteristics of the linear calibration function. It is applicable to methods requiring a calibration. Further parts of this International Standard will cover the determination of limit of detection and limit of determination, the effect of interferences and other performance characteristics.

It is intended especially for the evaluation of the pure analytical method and for the calculation of performance characteristics of the calibration function.

In order to derive comparable analytical results and as a basis for analytical quality control the calibration and evaluation of analytical methods have to be performed uniformly.

2 Definitions

For the purposes of this part of ISO 8466, the following definitions apply.

2.1 analytical method: An analytical method is composed of procedural, measuring, calibrating and evaluating instructions (see figure 1).

Whereas the procedural and measuring instructions depend on the method, and are therefore the object of standardization of the respective method, the calibrating and evaluating instructions are valid for any analytical method requiring calibration.

2.2 calibrating instruction: Describes the approach to determine the calibration function from information values, y_i , obtained by measuring given standard concentrations, x_i . The slope of the calibration function, b , as a measure of sensitivity of the analytical method and the standard deviation of the method, s_{x_0} , are figures of merit and characteristics which result from the calibration experiment.

The standard deviation, s_{x_0} , allows the comparison of independent analytical methods.

For the user of the method, these characteristics present criteria for the internal laboratory quality control.

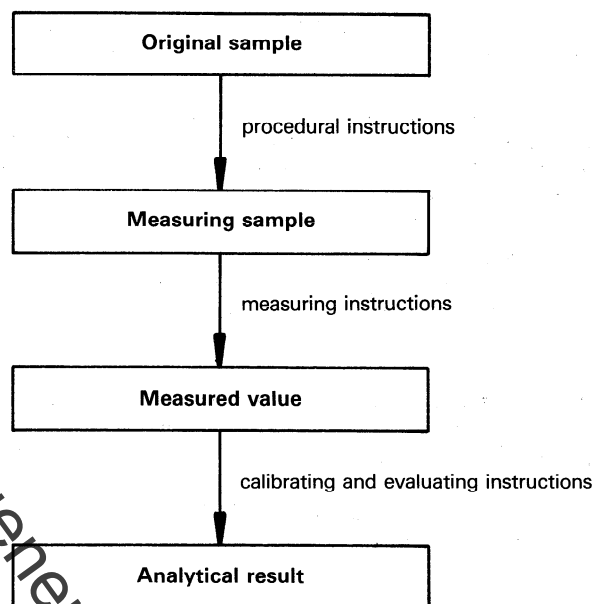


Figure 1 — The analytical method

2.3 evaluating instruction: A calculation guide for the computation of concentrations from the measured values by the use of the calibration function. Additionally, the confidence range permits an objective assessment of the imprecision of the analytical result^[2].

2.4 measured values: The concentration-dependent initial values (e.g. extinction) of a measuring system.

NOTE — Information value and measured volume are synonymous.

2.5 residual standard deviation, s_y : The residual standard deviation describes the scatter of the information values about the calculated regression line. It is a figure of merit, describing the precision of the calibration.

For the purpose of this standard, the standard deviation of the method means the standard of deviation of the calibration procedure.