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Kakovost vode - Umerjanje in vrednotenje analiznih metod - 1. del: Linearna umeritvena funkcija

Water quality - Calibration and evaluation of analytical methods - Part 1: Linear calibration function

Qualité de l'eau - Étalonnage et évaluation des méthodes d'analyse - Partie 1: Fonction linéaire d'étalonnage

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Second edition
2021-11

Water quality — Calibration and evaluation of analytical methods —

Part 1: Linear calibration function

Qualité de l'eau — Étalonnage et évaluation des méthodes d'analyse —

Partie 1: 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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 147, *Water quality,* Subcommittee SC 2, *Physical, chemical and biochemical methods*.

This second edition cancels and replaces the first edition (ISO 8466-1:1990), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the title has been modified;

— the scope of the document is the calibration for routine analysis;

— calculation of performance characteristics has been moved to the informative Annex A;

— the calibration range has been extended to several decade orders of magnitudes;

— the verification of the homogeneity of variances has been deleted;

— the linearity test has been modified;

— various calibration strategies have been described;

— the document has been editorially revised.

A list of all parts in the ISO 8466 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Calibration is a prerequisite for the quantification of analytes by means of physicochemical and chemical methods. In most cases, simple linear regression is applied because many measuring methods show a linear relationship between the indicated value and the sample content.

Since the publication of ISO 8466-1 in 1990, a huge progress has been made in the field of instrumental analysis, a consequence of which is that various calibration strategies have been developed in order to make best use of the equipment. The calibration range of many analytical methods was constrained to a maximum of one order of magnitude by the theoretical statistical requirement to only apply simple linear regression if homogeneity of variances exists across the selected working range. Due to the estimation of measurement uncertainty by calculation of the confidence interval in ISO 8466-1:1990, it had been necessary to conform to the required homogeneity of variances. Meanwhile, other methods for the estimation of measurement uncertainty that are independent of calibration have been established (e.g. ISO 11352).

Calibration is always done in two steps. The first step comprises the determination of the linear range, the second step is the calculation of the calibration function. The calibration strategies that are described in this document enable the analyst to individually define the calibration effort according to specified requirements. The method that is described in ISO 8466-1:1990 remains part of the informative annex since it can still be useful for specific purposes (e.g. method validation).

Water quality — Calibration and evaluation of analytical methods —

Part 1: Linear calibration function

1 Scope

This document specifies various calibration strategies for physicochemical and chemical analytical methods and specifies the calculation of analytical results.

It defines the general context for linear calibration so that individual standards dealing with analytical methods for the examination of water quality can make reference to it.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
working range
interval, determined by calibration, between the highest and the lowest content, where the lowest possible limit of the working range is the limit of quantification of the analytical method

3.2
one-point calibration
calibration between the origin and the indicated value corresponding to the content in the *calibration sample* (3.8)

3.3
two-point calibration
calibration using two *calibration samples* (3.8) with different contents at the upper and at the lower working range limit

3.4
indicated value
y
quantity value provided by a measuring instrument or a measuring system

Note 1 to entry: In accordance with definition 4.1 “indication” of ISO/IEC Guide 99[7].

3.5
content
general term for the quantitative expression of the concentration or fraction of a substance in or of a substance mixture

Note 1 to entry: For example, it is the generic term for mass concentration, molar concentration, mass fraction.

3.6
total procedure
analytical method comprising all steps from sample pre-treatment to the report of results

3.7
calibration solution
standard solution without a matrix

3.8
calibration sample
standard solution with a matrix

3.9
measurement procedure
comprises all details of a measurement including all calculations for obtaining the measurement result

3.10
responsivity
R
input–output gain of a detector system, i.e. indicated value divided by the corresponding content in the *calibration sample* (3.8)

Note 1 to entry: For a system that responds linearly to its input, there is a unique responsivity. For nonlinear systems, the responsivity is the local slope.

4 Symbols

A_s	recovery rate for the sample
A_{Is}	recovery rate of the internal standard
a	intercept of the calibration line or the regression line for standard addition
b	slope of the calibration line or the regression line for standard addition or the coefficient of the linear term of the second-order calibration function
b_i	point-to-point slope i
b_m	median of the slopes b_i
c	regression coefficient of the quadratic term of the second-order calibration function
F	factor (taking into account sample preparation, e.g. enrichment factor)
f	conversion factor (e.g. 100 for expression in %)
f_1 or f_2	degree of freedom
i	index of the calibration solutions (1, 2, …, N)
m	number of replicate measurements per spiking level for standard addition
N	number of calibration solutions

n	number of spiking levels for the method of standard addition (including unspiked sample)
P	confidence level
R	responsivity
R_0	responsivity threshold
R_m	responsivity median
V_{ssi}	volume of the spiking solution i
V_M	volume of the measurement solution
V_s	volume of the sample
V_{su}	volume of the sub-samples
x	analyte content
$\bar{x}$	mean value of the contents x_i
x_e	analyte content in the calibration solution
x_{eg}	analyte content in the spiked calibration sample
x_g	analyte content in the sample after calibration of the total procedure
x_{Ie}	content of the internal standard I in the calibration solution
x_{Ieg}	content of the internal standard I in the calibration sample
x_{Ig}	content of the internal standard I in the sample
x_{IM}	measured content of the internal standard I in the measurement solution
x_i	analyte content in the calibration solution i
x_M	analyte content in the measurement solution
x_o	analyte content in the original sample
x_s	analyte content in the sample
x_{sp}	content of the spiked sample
x_{ss}	content of the spiking solution
x_z	spiked content in the sample
x_{zi}	spiked content in the sub-samples i
y	indicated value
$\bar{y}$	mean value of the indicated values y_i
y_e	indicated value for external calibration
y_{eg}	indicated value for external calibration of the total procedure
y_g	indicated value of the analyte in the sample

y_{Ie} indicated value of the internal standard I for calibration of the measuring method

y_{Ieg} indicated value of the internal standard I for calibration of the total procedure

y_{Ig} indicated value of the internal standard I in the sample

y_i indicated value of the calibration solution *i* or indicated value of the sub-sample *i* for standard addition

y_s indicated value of the (unspiked) sample

Δb_{i-m} difference between the slope b_i and the median of the slopes b_m

5 Determination of the linear working range and establishment of the calibration range

5.1 General

Linearity of the analytical measuring method is tested within the practice-oriented working range in accordance with the following pattern:

a) First step: Establishment of the preliminary working range.

Prepare and analyse calibration solutions (with or without internal standards, analyte-dependent but matrix-independent) over one or more orders of magnitude.

b) Second step: Test linearity and establishment of the linear working range.

Calculate the linear calibration function.

5.2 Preliminary choice of working range

Each calibration starts with the selection of a preliminary working range. This is subject to:

— the objective with respect to the practical application;

— the technically feasible possibilities;

— the linearity of the functional relationship between the indicated values and the contents.

The working range should largely cover a wide application range for the purpose in hand.

The available measuring instruments often allow the choice of a wide linear working range (sometimes over several orders of magnitude). On the other hand, it is required that the indicated values obtained near the lower limit of the working range can be at least distinguished from the indicated values of the procedure blank. A lower limit of the working range is only reasonable if it is greater than or equal to the limit of quantification of this method. Moreover, dilution and concentration steps are required to be feasible and accurate.

5.3 Estimation of the linear working range

5.3.1 General

For testing the linearity of a working range covering one or more orders of magnitude, the following procedure which is based on the first-order calibration function has proved to be effective.

Prepare a minimum of five calibration solutions with different contents (x_i) and determine the corresponding indicated values (y_i). Subsequently, plot both the measuring points and the point-to-point slopes in a diagram and visually estimate the linear working range (see 5.3.2).