



SLOVENSKI STANDARD

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Kakovost vode - Ocena merilne negotovosti na osnovi podatkov, pridobljenih z validacijo in kontrolo kakovosti

Water quality - Estimation of measurement uncertainty based on validation and quality control data

Qualité de l'eau - Estimation de l'incertitude de mesure basée sur des données de validation et de contrôle qualité

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ICS:

13.060.45	Preiskava vode na splošno	Examination of water in general
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en,fr,de

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**International
Standard**

ISO 11352

**Water quality — Estimation of
measurement uncertainty based on
validation and quality control data**

*Qualité de l'eau — Estimation de l'incertitude de mesure basée
sur des données de validation et de contrôle qualité*

**Second edition
2025-09**

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CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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).

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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 11352:2012), which has been technically revised.

The main changes are as follows:

- requirements for measurements for estimation of uncertainty component for the within-laboratory reproducibility have been changed from at least eight to 20 replicates with exception of a first estimation;
- the use of data from target control charts estimation of precision has been described;
- a new informative annex has been introduced to describe how to divide the measurement range into two parts for constant absolute and constant relative uncertainties;
- in [Annex B](#) (former Annex A) the estimation of the standard uncertainty from range control charts has been changed to the use of pooled standard deviation;
- the examples in [Annex C](#) have been adjusted;
- this document has been editorially revised.

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.

ISO 11352:2025(en)**Introduction**

The basic principles of the estimation of measurement uncertainty are set out in ISO/IEC Guide 98-3.^[1] There are several ways of estimating measurement uncertainty depending on the purpose of the estimation and the available data; Eurolab TR 1/2007^[2] gives an overview of the main approaches.

This document specifies a set of procedures to enable laboratories to estimate the measurement uncertainty of their results, using an approach based on validation and quality control data. Validation data can be used for first estimates of the measurement uncertainty, but should later be confirmed with data from quality control, when the method is in routine use. It is structured in a way that is applicable to analysts that do not have a thorough understanding of metrology or statistics.

Nordtest TR 537^[3] has been used as a basis for developing this document. The approach taken is “top-down”, contrary to the mainly “bottom-up” strategy adopted in ISO/IEC Guide 98-3^[1].

It is statistically acceptable to combine the uncertainty components associate with within-laboratory reproducibility for random error and the uncertainty associated the bias for systematic error into a single measure of uncertainty. The sources of data for this approach are validation and analytical quality control. The experimental approach specified in this document enables a good coverage of the sources of variation observed during routine use of the analytical method.

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Water quality — Estimation of measurement uncertainty based on validation and quality control data

1 Scope

This document specifies approaches for the estimation of measurement uncertainty of chemical and physicochemical methods in single laboratories based on validation data and quality control data obtained within the field of water analysis. However, this approach can also be used in many other areas of chemical analysis.

NOTE 1 The principles of the estimation of uncertainty specified in this document are consistent with the principles described in ISO/IEC Guide 98-3.

In this document, the quantification of measurement uncertainty relies on performance characteristics of a measurement procedure obtained from validation and the results of internal and external quality control.

NOTE 2 The approaches specified in this document are mainly based on Nordtest TR 537^[3], but also QUAM^[4], and Eurolab TR 1/2007^[2].

NOTE 3 This document only addresses the evaluation of measurement uncertainty for results obtained from quantitative measurement procedures. The uncertainties associated with results obtained from qualitative procedures are not considered.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC Guide 99 and the following apply.

ISO and IEC maintain terminology 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

precision

measurement precision

closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions

[SOURCE: ISO/IEC Guide 99:2007 2.15, modified — Notes 1 to 4 to entry have been deleted.]

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3.2

error**measurement error**

measured quantity value minus a reference quantity value

[SOURCE: ISO/IEC Guide 99:2007, 2.16, modified — the admitted term "error of measurement" and Notes 1 and 2 to entry have been deleted.]

3.3

systematic error**systematic measurement error**

component of *measurement error* (3.2) that in replicate measurements remains constant or varies in a predictable manner

[SOURCE: ISO/IEC Guide 99:2007, 2.17, modified — the admitted term "systematic error of measurement" and Notes 1 to 3 to entry have been deleted.]

3.4

bias**measurement bias**

estimate of a *systematic measurement error* (3.3)

[SOURCE: ISO/IEC Guide 99:2007, 2.18]

3.5

random error**random measurement error**

component of *measurement error* (3.2) that in replicate measurements varies in an unpredictable manner

[SOURCE: ISO/IEC Guide 99:2007, 2.19, modified — Notes 1 to 3 to entry have been deleted.]

3.6

repeatability condition

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

[SOURCE: ISO/IEC Guide 99:2007, 2.20, modified — the term "repeatability condition of measurement" and Notes 1 and 2 to entry have been deleted.]

3.7

repeatability

measurement precision (3.1) under a set of *repeatability conditions* (3.6) of measurement

[SOURCE: ISO/IEC Guide 99:2007, 2.21, modified — the term "measurement repeatability" has been deleted.]

3.8

analytical run

series of measurements made under *repeatability conditions* (3.6)

3.9

within-laboratory reproducibility

intermediate *measurement precision* (3.1) where all variations that occur within one laboratory are included

Note 1 to entry: Intermediate measurement precision is defined in ISO/IEC Guide 99: 2007, 2.23.

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3.10

reproducibility condition

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

[SOURCE: ISO/IEC Guide 99:2007, 2.24, modified — the term "reproducibility condition of measurement" Notes 1 and 2 to entry have been deleted.]

3.11

reproducibility

measurement precision (3.1) under *reproducibility conditions* (3.10) of measurement

[SOURCE: ISO/IEC Guide 99:2007, 2.25, modified — the term "measurement reproducibility" and Note 1 to entry have been deleted.]

3.12

uncertainty**measurement uncertainty**

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

[SOURCE: ISO/IEC Guide 99:2007, 2.26, modified — Notes 1 to 4 to entry have been deleted.]

3.13

standard uncertainty**standard measurement uncertainty**

measurement uncertainty (3.12) expressed as a standard deviation

[SOURCE: ISO/IEC Guide 99:2007, 2.30, modified — the admitted term "standard uncertainty of measurement" has been deleted.]

3.14

combined standard uncertainty**combined standard measurement uncertainty**

standard measurement uncertainty (3.13) that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model

[SOURCE: ISO/IEC Guide 99:2007, 2.31, modified — Note 1 to entry has been deleted.]

3.15

target measurement uncertainty**target uncertainty**

measurement uncertainty (3.12) specified as an upper limit and decided on the basis of the intended use of measurement results

[SOURCE: ISO/IEC Guide 99:2007, 2.34]

3.16

expanded uncertainty**expanded measurement uncertainty**

product of a *combined standard measurement uncertainty* (3.14) and a factor larger than the number one

Note 1 to entry: The term "factor" in this definition refers to a *coverage factor* (3.17).

[SOURCE: ISO/IEC Guide 99:2007, 2.35, modified — Notes 1 and 3 to entry have been deleted.]

3.17

coverage factor

number larger than one by which a *combined standard measurement uncertainty* (3.14) is multiplied to obtain an *expanded measurement uncertainty* (3.16)

[SOURCE: ISO/IEC Guide 99:2007, 2.38, modified — Note 1 to entry has been deleted.]

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3.18

quality control sample

reference material used for quality control

Note 1 to entry: For more information on reference materials, see ISO Guide 30.^[6]

Note 2 to entry: Quality control samples may or may not have a reference value.

4 Symbols

b	bias estimated as the difference between mean measured value and an accepted reference value
b_i	i^{th} bias of a series of biases estimated as the difference between mean measured value and an accepted reference value
b_{rms}	root mean square (quadratic mean) of the b_i values
c	concentration
c_T	transition point between absolute and relative uncertainties
D_i	difference between the measurement result and the assigned value of the i^{th} sample of the inter-laboratory comparison
D_{rms}	root mean square (quadratic mean) of the differences
i	variable related to an observation of a series
j	variable related to a source of uncertainty
J	total number of sources of uncertainty
k	coverage factor
n_{ilc}	number of analysed interlaboratory comparison samples
n_M	number of measurements
$n_{p,i}$	number of participating laboratories for sample i
n_r	number of reference materials
n_η	number of recovery experiments
s	standard deviation
s_b	standard deviation of the measured values of the reference material
s_p	pooled standard deviation
$s_{R,i}$	reproducibility standard deviation from the interlaboratory comparison for sample i
s_{R_w}	within-laboratory reproducibility standard deviation
$s_{R_w, \text{rel}}$	relative within-laboratory reproducibility standard deviation
U	expanded uncertainty
U_{rel}	relative expanded uncertainty
u_c	combined standard uncertainty