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Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation

Lignes directrices relatives à l'utilisation d'estimations de la répétabilité, de la reproductibilité et de la justesse dans l'évaluation de l'incertitude de mesure

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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 on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 6, *Measurement methods and results*.

This second edition cancels and replaces the first edition (ISO 21748:2010), of which it constitutes a minor revision.

The changes compared to the previous edition are as follows:

— minor change in the title (estimation to evaluation) to reflect preferred use of terms (see third list item);

— minor changes in wording and format to conform to current ISO Directives, which included the addition of Clause 2 and renumbering of subsequent clauses;

— the phrases "estimation of measurement uncertainty" (and similar usage of "estimate") and "evaluation of measurement uncertainty" (and similar usage of "evaluate") have been amended to distinguish quantitative estimates of the components of uncertainty from the process of evaluations of measurement uncertainty, which can include additional relevant considerations;

— the word "standard" has been added before "uncertainty" where appropriate, for clarity;

— redundant definitions of terms defined as squared quantities, where the standard deviation was also defined [$s^2{}_b$, $s^2{}_{inh}$, $s^2{}_L$, $s^2{}_r$, $s^2{}_W$, $u^2(y)$, $\sigma^2{}_L$, $\sigma^2{}_r$] have been removed;

— in the definition of r_{ij}, "in the interval -1 to +1" was removed;

— in the definition of the term s_{inh}, "uncertainty" was changed to "standard deviation";

— in the definitions for $u(y)$, $u_i(y)$ and $u(Y)$, $U(y)$, equations were removed (not necessary for standard terms);

— the symbols from all definitions of terms where they had been included (combined standard uncertainty, coverage factor, expanded uncertainty, standard uncertainty) have been removed;

- the definition of y_0 has been removed because the term is not used in the document;
- in 7.4, first dash, “quality control charts” has been replaced with “control charts”;
- a note has been added to Clause 10 (previously Clause 9);
- in 13.1, 14.1 and 14.3 (previously 12.1, 13.1 and 13.3), “combined” has been added before “standard uncertainty”;
- in 13.2.1 and 13.2.2 (previously 12.2.1 and 12.2.2), the word “combined” has been removed before “expanded uncertainty”;
- in A.1, changed italics “standard uncertainties” to standard text;
- in A.1, 7th paragraph (3rd from end), “combined standard uncertainties [$u(x_i)$]” has been changed to “additional standard uncertainties $u(y)$”;
- in C.3, title, “Uncertainty for AOAC method 990.12” has been replaced with “Uncertainty for measurements obtained by AOAC method 990.12”;
- in C.3.2, “eight laboratories” has been replaced with “twelve laboratories “;
- in C.4.4, “0,07 g/kg (0,7 % as mass fraction)” has been changed to “7 g/kg (0,7 % as mass fraction)”;
- References [27] and [28] have been updated.

Introduction

Knowledge of the uncertainty associated with measurement results is essential to the interpretation of the results. Without quantitative evaluations of uncertainty, it is impossible to decide whether observed differences between results reflect more than experimental variability, whether test items comply with specifications, or whether laws based on limits have been broken. Without information on uncertainty, there is a risk of misinterpretation of results. Incorrect decisions taken on such a basis can result in unnecessary expenditure in industry, incorrect prosecution in law, or adverse health or social consequences.

Laboratories operating under ISO/IEC 17025 accreditation and related systems are accordingly required to evaluate measurement uncertainty for measurement and test results and report the uncertainty where relevant. ISO/IEC Guide 98-3 is a widely adopted standard approach. However, it applies to situations where a model of the measurement process is available. A very wide range of standard test methods is, however, subjected to collaborative study in accordance with ISO 5725-2. This document provides an appropriate and economic methodology for estimating uncertainty associated with the results of these methods, which complies fully with the relevant principles of the GUM, while taking account of method performance data obtained by collaborative study.

The general approach used in this document requires the following.

— Estimates of the repeatability, reproducibility and trueness of the method in use, obtained by collaborative study as described in ISO 5725-2, be available from published information about the test method in use. These provide estimates of the intra-laboratory and inter-laboratory components of variance, together with an estimate of uncertainty associated with the trueness of the method.

— The laboratory confirms that its implementation of the test method is consistent with the established performance of the test method by checking its own bias and precision. This confirms that the published data are applicable to the results obtained by the laboratory.

— Any influences on the measurement results that were not adequately covered by the collaborative study be identified and the variance associated with the results that could arise from these effects be quantified.

An uncertainty estimate is made by combining the relevant variance estimates in the manner prescribed by the GUM. This estimate can serve, with other contributions, in the evaluation of uncertainty, or in some cases can be the final, stated, uncertainty.

The general principle of using reproducibility data in uncertainty evaluation is sometimes called a "top-down" approach.

The dispersion of results obtained in a collaborative study is often also usefully compared with measurement uncertainty evaluated using GUM procedures as a test of full understanding of the method. Such comparisons will be more effective given a consistent methodology for estimating the same parameter using collaborative study data.

Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty evaluation

1 Scope

This document gives guidance for

— evaluation of measurement uncertainties using data obtained from studies conducted in accordance with ISO 5725-2, and

— comparison of collaborative study results with measurement uncertainty (MU) obtained using formal principles of uncertainty propagation (see Clause 14).

ISO 5725-3 provides additional models for studies of intermediate precision. However, while the same general approach may be applied to the use of such extended models, uncertainty evaluation using these models is not incorporated in this document.

This document is applicable to all measurement and test fields where an uncertainty associated with a result has to be determined.

This document does not describe the application of repeatability data in the absence of reproducibility data.

This document assumes that recognized, non-negligible systematic effects are corrected, either by applying a numerical correction as part of the method of measurement, or by investigation and removal of the cause of the effect.

The recommendations in this document are primarily for guidance. It is recognized that while the recommendations presented do form a valid approach to the evaluation of uncertainty for many purposes, it is also possible to adopt other suitable approaches.

In general, references to measurement results, methods and processes in this document are normally understood to apply also to testing results, methods and processes.

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.

NOTE Reference is made to "intermediate precision conditions", which are discussed in detail in ISO 5725-3.

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

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

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

3.1
bias
difference between the expectation of a test result or measurement result and a true value

Note 1 to entry: Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to the bias. A larger systematic difference from the true value is reflected by a larger bias value.

Note 2 to entry: The bias of a measuring instrument is normally estimated by averaging the error of indication over an appropriate number of repeated measurements. The error of indication is the "indication of a measuring instrument minus a true value of the corresponding input quantity".

Note 3 to entry: In practice, the accepted reference value is substituted for the true value.

[SOURCE: ISO 3534-2:2006, 3.3.2]

3.2
combined standard uncertainty
standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities, equal to the positive square root of a sum of terms, the terms being the variances or covariances of these other quantities weighted according to how the measurement result varies with changes in these quantities

[SOURCE: ISO/IEC Guide 98-3:2008, 2.3.4]

3.3
coverage factor
numerical factor used as a multiplier of the *combined standard uncertainty* (3.2) in order to obtain an *expanded uncertainty* (3.4)

Note 1 to entry: A coverage factor, k, is typically in the range from 2 to 3.

[SOURCE: ISO/IEC Guide 98-3:2008, 2.3.6]

3.4
expanded uncertainty
quantity defining an interval about a result of a measurement expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurand

Note 1 to entry: The fraction may be regarded as the coverage probability or level of confidence of the interval.

Note 2 to entry: To associate a specific level of confidence with the interval defined by the expanded uncertainty requires explicit or implicit assumptions regarding the probability distribution characterized by the measurement result and its *combined standard uncertainty* (3.2). The level of confidence that may be attributed to this interval can be known only to the extent to which such assumptions can be justified.

Note 3 to entry: Expanded uncertainty is termed overall uncertainty in paragraph 5 of Reference [20].

[SOURCE: ISO/IEC Guide 98-3:2008, 2.3.5]

3.5
precision
closeness of agreement between independent test/measurement results obtained under stipulated conditions

Note 1 to entry: Precision depends only on the distribution of random errors and does not relate to the true value or the specified value.

Note 2 to entry: The measure of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results or measurement results. Less precision is reflected by a larger standard deviation.

Note 3 to entry: Quantitative measures of precision depend critically on the stipulated conditions. *Repeatability conditions* (3.7) and *reproducibility conditions* (3.10) are particular sets of extreme stipulated conditions.

[SOURCE: ISO 3534-2:2006, 3.3.4]

3.6
repeatability
precision (3.5) under *repeatability conditions* (3.7)

Note 1 to entry: Repeatability can be expressed quantitatively in terms of the dispersion characteristics of the results.

[SOURCE: ISO 3534-2:2006, 3.3.5]

3.7
repeatability conditions
observation conditions where independent test/measurement results are obtained with the same method on identical test/measurement items in the same test or measuring facility by the same operator using the same equipment within short intervals of time

Note 1 to entry: Repeatability conditions include the following:

— the same measurement procedure or test procedure;

— the same operator;

— the same measuring or test equipment used under the same conditions;

— the same location;

— repetition over a short period of time.

[SOURCE: ISO 3534-2:2006, 3.3.6]

3.8
repeatability standard deviation

standard deviation of test results or measurement results obtained under *repeatability conditions* (3.7)

Note 1 to entry: It is a measure of the dispersion of the distribution of test or measurement results under repeatability conditions.

Note 2 to entry: Similarly, "repeatability variance" and "repeatability coefficient of variation" can be defined and used as measures of the dispersion of test or measurement results under repeatability conditions.

[SOURCE: ISO 3534-2:2006, 3.3.7]

3.9
reproducibility
precision (3.5) under *reproducibility conditions* (3.10)

Note 1 to entry: Reproducibility can be expressed quantitatively in terms of the dispersion characteristics of the results.

Note 2 to entry: Results are usually understood to be corrected results.

[SOURCE: ISO 3534-2:2006, 3.3.10]

3.10
reproducibility conditions
observation conditions where independent test/measurement results are obtained with the same method on identical test/measurement items in different test or measurement facilities with different operators using different equipment

[SOURCE: ISO 3534-2:2006, 3.3.11]

3.11
reproducibility standard deviation
standard deviation of test results or measurement results obtained under *reproducibility conditions* (3.10)

Note 1 to entry: It is a measure of the dispersion of the distribution of test or measurement results under reproducibility conditions.

Note 2 to entry: Similarly, "reproducibility variance" and "reproducibility coefficient of variation" can be defined and used as measures of the dispersion of test or measurement results under reproducibility conditions.

[SOURCE: ISO 3534-2:2006, 3.3.12]

3.12
standard uncertainty
uncertainty (3.14) of the result of a measurement expressed as a standard deviation

[SOURCE: ISO/IEC Guide 98-3:2008, 2.3.1]

3.13
trueness
closeness of agreement between the expectation of a test result or a measurement result and a true value

Note 1 to entry: The measure of trueness is usually expressed in terms of *bias* (3.1).

Note 2 to entry: Trueness is sometimes referred to as "accuracy of the mean". This usage is not recommended.

Note 3 to entry: In practice, the accepted reference value is substituted for the true value.

[SOURCE: ISO 3534-2:2006, 3.3.3]

3.14
uncertainty

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

Note 1 to entry: 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.

Note 2 to entry: Uncertainty of measurement comprises, in general, many components. Some of these components may be estimated from the statistical distribution of the results of a series of measurements and can be characterized by experimental standard deviations. Other components, which also can be characterized by standard deviations, are estimated from assumed probability distributions based on experience or other information.

Note 3 to entry: 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.

[SOURCE: ISO/IEC Guide 98-3:2008, 2.2.3]

3.15
uncertainty budget
list of sources of *uncertainty* (3.14) and their associated standard uncertainties, compiled with a view to evaluating a *combined standard uncertainty* (3.2) associated with a measurement result

Note 1 to entry: The list often includes additional information such as sensitivity coefficients (change of result with change in a quantity affecting the result), degrees of freedom for each standard uncertainty, and an identification of the means of estimating each standard uncertainty in terms of a Type A or Type B evaluation (see ISO/IEC Guide 98-3).

4 Symbols

a coefficient indicating an intercept in the empirical relationship $\hat{s}_R = a + bm$

B laboratory component of bias

b coefficient indicating a slope in the empirical relationship $\hat{s}_R = a + bm$

c coefficient in the empirical relationship $\hat{s}_R = cm^d$

c_i sensitivity coefficient $\partial y / \partial x_i$

d coefficient indicating an exponent in the empirical relationship $\hat{s}_R = cm^d$

e random error under repeatability conditions

k numerical factor used as a multiplier of the combined standard uncertainty u in order to obtain an expanded uncertainty U

l laboratory number

m mean value of the measurements

N number of contributions included in combined uncertainty calculations

n' number of contributions incorporated in combined uncertainty calculations in addition to collaborative study data

n_l number of replicates by laboratory l in the study of a certified reference material

n_r number of replicate measurements

p number of laboratories

Q number of test items from a larger batch

q number of assigned values by consensus during a collaborative study

r_{ij} correlation coefficient between x_i and x_j

s_b between-group component of variance expressed as a standard deviation

s_D estimated, or experimental, standard deviation of results obtained by repeated measurement on a reference material used for checking control of bias

s_inh standard deviation associated with the inhomogeneity of the sample

s_l estimated repeatability standard deviation with ν_l degrees of freedom for laboratory l during verification of repeatability

s_L experimental or estimated inter-laboratory standard deviation

$\hat{s}_\mathrm{L}$ adjusted estimate of standard deviation associated with B where s_L is dependent on the response

s_r estimate of intra-laboratory standard deviation; the estimated standard deviation for e

s'_r adjusted estimate of intra-laboratory standard deviation, where the contribution is dependent on the response