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

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 21748 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 6, *Measurement methods and results*.

This first edition cancels and replaces ISO/TS 21748:2004, which has been technically revised.

Introduction

Knowledge of the uncertainty associated with measurement results is essential to the interpretation of the results. Without quantitative assessments 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 may 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. The *Guide to the expression of uncertainty in measurement* (GUM), published by ISO/IEC as ISO/IEC Guide 98-3:2008, 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 5725-2:1994. This International Standard 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, whilst taking account of method performance data obtained by collaborative study.

The general approach used in this International Standard requires that

— estimates of the repeatability, reproducibility and trueness of the method in use, obtained by collaborative study as described in ISO 5725-2:1994, be available from published information about the test method in use. These provide estimates of the intra- 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.

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 estimates obtained 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 estimation

1 Scope

The International Standard gives guidance for

- evaluation of measurement uncertainties using data obtained from studies conducted in accordance with ISO 5725-2:1994;
- comparison of collaborative study results with measurement uncertainty (MU) obtained using formal principles of uncertainty propagation (see Clause 13).

ISO 5725-3:1994 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 the present International Standard.

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

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

This International Standard 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 International Standard 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 International Standard are normally understood to apply also to testing results, methods and processes.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply. In addition, reference is made to “intermediate precision conditions”, which are discussed in detail in ISO 5725-3:1994.

2.1
bias
difference between the expectation of a test result or measurement result and a true value

NOTE 1 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 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 In practice, the accepted reference value is substituted for the true value.

[ISO 3534-2:2006, definition 3.3.2]

2.2
combined standard uncertainty
u(*y*)
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

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

2.3
coverage factor
k
numerical factor used as a multiplier of the combined standard uncertainty in order to obtain an expanded uncertainty

NOTE A coverage factor, *k*, is typically in the range 2 to 3.

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

2.4
expanded uncertainty
U
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 The fraction may be regarded as the coverage probability or level of confidence of the interval.

NOTE 2 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. 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 Expanded uncertainty is termed overall uncertainty in paragraph 5 of Recommendation INC-1 (1980).

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

2.5
precision
closeness of agreement between independent test/measurement results obtained under stipulated conditions

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

NOTE 2 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 Quantitative measures of precision depend critically on the stipulated conditions. Repeatability conditions and reproducibility conditions are particular sets of extreme stipulated conditions.

[ISO 3534-2:2006, definition 3.3.4]

2.6
repeatability
precision under repeatability conditions

NOTE Repeatability can be expressed quantitatively in terms of the dispersion characteristics of the results.

[ISO 3534-2:2006, definition 3.3.5]

2.7
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 Repeatability conditions include:

— 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.

[ISO 3534-2:2006, definition 3.3.6]

2.8
repeatability standard deviation
standard deviation of test results or measurement results obtained under repeatability conditions

NOTE 1 It is a measure of the dispersion of the distribution of test or measurement results under repeatability conditions.

NOTE 2 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.

[ISO 3534-2:2006, definition 3.3.7]

2.9
reproducibility
precision under reproducibility conditions

NOTE 1 Reproducibility can be expressed quantitatively in terms of the dispersion characteristics of the results.

NOTE 2 Results are usually understood to be corrected results.

[ISO 3534-2:2006, definition 3.3.10]

2.10
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

[ISO 3534-2:2006, definition 3.3.11]

2.11
reproducibility standard deviation
standard deviation of test results or measurement results obtained under reproducibility conditions

NOTE 1 It is a measure of the dispersion of the distribution of test or measurement results under reproducibility conditions.

NOTE 2 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.

[ISO 3534-2:2006, definition 3.3.12]

2.12
standard uncertainty

$u(x_i)$

uncertainty of the result of a measurement expressed as a standard deviation

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

2.13
trueness

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

NOTE 1 The measure of trueness is usually expressed in terms of bias.

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

NOTE 3 In practice, the accepted reference value is substituted for the true value.

[ISO 3534-2:2006, definition 3.3.3]

2.14
uncertainty

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

NOTE 1 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 Uncertainty of measurement comprises, in general, many components. Some of these components may be evaluated 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 evaluated from assumed probability distributions based on experience or other information.

NOTE 3 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.

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

2.15
uncertainty budget

list of sources of uncertainty and their associated standard uncertainties, compiled with a view to evaluating a combined standard uncertainty associated with a measurement result

NOTE 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 evaluating each standard uncertainty in terms of a Type A or Type B evaluation (see ISO/IEC Guide 98-3:2008).

3 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, in the interval −1 to +1

s_{b} between-group component of variance expressed as a standard deviation

s_{b}^2 between-group component of variance

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} uncertainty associated with the inhomogeneity of the sample

s_{inh}^2 component of variance 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

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

s_{L}^2 estimated variance of B

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

s_r^2 estimated variance of e

s_R estimated reproducibility standard deviation

s'_R estimate of the reproducibility standard deviation adjusted for laboratory estimate of repeatability standard deviation

$\hat{s}_R$ adjusted estimate of reproducibility standard deviation calculated from an empirical model, where the contributions are dependent on the response

s_w estimate of intra-laboratory standard deviation derived from replicates or other repeatability studies

s_w^2 estimated intra-group component of variance (often an intra-laboratory component of variance)

$s_{\hat{\delta}}$ estimated standard deviation of bias $\hat{\delta}$ measured in a collaborative study

$s(\Delta_y)$ laboratory standard deviation of differences during a comparison of a routine method with a definitive method or with values assigned by consensus

$u(\hat{\delta})$ uncertainty associated with δ due to the uncertainty of estimating δ by measuring a reference measurement standard or reference material with certified value $\hat{\mu}$

$u(\hat{\mu})$ uncertainty associated with the certified value $\hat{\mu}$

$u(x_i)$ uncertainty associated with the input value x_i; also uncertainty associated with x'_i where x_i and x'_i differ only by a constant

$u(y)$ combined standard uncertainty associated with y where $u(y) = \sqrt{\sum_{i=1,n} c_i^2 u^2(x_i)}$

$u_i(y)$ contribution to combined uncertainty in y associated with the value x_i. In terms of the definition of $u(y)$ above, $u_i(y) = c_i u(x_i)$

$u(y_i)$ combined standard uncertainty associated with result or assigned value y_i

$u(Y)$ combined uncertainty for the result $Y = f(y_1, y_2, ...)$ where $u(Y) = \sqrt{\sum_i [c_i u(y_i)]^2}$

$u^2(y)$ combined standard uncertainty associated with y, expressed as a variance

u_{inh} uncertainty associated with sample inhomogeneity

U expanded uncertainty, equal to k times the standard uncertainty u

$U(y)$ expanded uncertainty in y where $U(y) = ku(y)$, where k is a coverage factor

x_i value of the ith input quantity in the determination of a result

x'_i deviation of the ith input value from the nominal value of x

Y combined result formed as a function of other results y_i

y_i result for test item i from the definitive method during a comparison of methods or assigned value in a comparison with values assigned by consensus

$\hat{y}_i$ result for test item i from the routine test method during a comparison of methods

y_0 assigned value for proficiency testing

Δ laboratory bias

Δ_l estimate of bias of laboratory l, equal to the laboratory mean, m, minus the certified value, $\hat{\mu}$

$\bar{\Delta}_y$ mean laboratory bias during a comparison of a routine method with a definitive method or with values assigned by consensus

δ bias intrinsic to the measurement method in use

$\hat{\delta}$ estimated or measured bias

μ unknown expectation of the ideal result

$\hat{\mu}$ certified value of a reference material

σ_0 standard deviation for proficiency testing

σ_D true value of the standard deviation of results obtained by repeated measurement on a reference material used for checking control of bias

σ_L inter-laboratory standard deviation; standard deviation of B

σ_L^2 variance of B; inter-laboratory variance

σ_r intra-laboratory standard deviation; standard deviation of e

σ_r^2 variance of e; intra-laboratory variance

σ_w within-group standard deviation

σ_{w0} standard deviation required for adequate performance (see ISO Guide 33)

ν_{eff} effective degrees of freedom for the standard deviation of, or uncertainty associated with, a result y_i

ν_i degrees of freedom associated with the ith contribution to uncertainty

ν_l degrees of freedom associated with an estimate s_l of the standard deviation for laboratory l during verification of repeatability

4 Principles

4.1 Individual results and measurement process performance

4.1.1 Measurement uncertainty relates to individual results. Repeatability, reproducibility and bias, by contrast, relate to the performance of a measurement or testing *process*. For studies under all parts of ISO 5725, the measurement or testing process will be a single measurement method, used by all laboratories taking part in the study. Note that for the purposes of this International Standard, the measurement method is assumed to be implemented in the form of a single detailed measurement procedure (as defined in ISO/IEC Guide 99:2007, 2.6). It is implicit in this International Standard that process-performance figures derived from method-performance studies are relevant to all individual measurement results produced by the process. It will be seen that this assumption requires supporting evidence in the form of appropriate quality control and assurance data for the measurement process (Clause 6).

4.1.2 It will be seen below that differences between individual test items may additionally need to be taken into account, but, with that caveat, it is unnecessary to undertake individual and detailed uncertainty studies for every test item for a well-characterized and stable measurement process.

4.2 Applicability of reproducibility data

The application of this International Standard is based on two principles.

— First, the reproducibility standard deviation obtained in a collaborative study is a valid basis for measurement uncertainty evaluation (see A.2.1).

— Second, effects not observed within the context of the collaborative study must be demonstrably negligible or explicitly allowed for. The latter principle is implemented by an extension of the basic model used for collaborative study (see A.2.3).

