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Statistical methods — Guidelines for the evaluation of conformity with specified requirements

Méthodes statistiques — Lignes directrices pour l'évaluation de la conformité à des exigences spécifiques

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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 69, *Applications of statistical methods*, Subcommittee SC 6, *Measurement methods and results*.

This first edition of ISO 10576 cancels and replaces ISO 10576-1:2003, which has been technically revised.

The main changes are as follows:

— examples were updated to incorporate lab-to-lab variability in the uncertainty calculations, see Annex B.

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

Conformity assessment is a systematic examination of the extent to which an entity conforms to a specified criterion. The objective is to provide assurance of conformity, either in the form of a supplier's declaration, or of a third-party certification (see ISO/IEC Guide 2, 2004). A specification is usually formulated as a single limiting value, LV, or as a set of (upper and lower) limiting values for a measurable characteristic. When the specification refers, e.g. to health-related characteristics, the limiting values are sometimes termed threshold limit value TLV, or permissible exposure limits, PEL.

Whenever conformity assessment involves measurement or sampling uncertainty, it is common practice to invoke elements from the theory of statistical hypothesis testing to provide a formal procedure. With the knowledge of the measurement procedure and of its behaviour with regard to the uncertainty of its outcomes, it is possible to estimate and control the risk of making erroneous declarations of conformity or non-conformity to the specifications. An operational way of formulating requirements of assurance is to require that the risk of (erroneously) declaring a non-conforming entity to be conforming should be small. Consequently, it is necessary to tolerate a (large) risk that an entity, which only marginally conforms, will fail to be declared as conforming. Applying a two-stage procedure instead of a one-stage procedure can decrease this risk.

When a test for non-conformity is performed, similar considerations apply.

In this document, this issue is addressed in respect of the testing of output from production or service processes for conformity and non-conformity with specifications.

Because of the apparent similarity to acceptance sampling procedures, it is sometimes seen that acceptance sampling plans are used in conformity assessment activities. Acceptance sampling and conformity assessment activities both utilize elements of hypothesis testing (see e.g. ISO 2854[2]). It is, however, important to realise that the objectives of the two activities are fundamentally different and in particular the two activities imply different approaches to the risk involved (see ISO 2854[2] and Holst[9]).

This document examines conformity assessment from a frequentist perspective. ISO/IEC Guide 98-4 examines conformity assessment from a Bayesian perspective. A comparison of these two approaches plus the fiducial approach is given in ISO/TR 13587.

Statistical methods — Guidelines for the evaluation of conformity with specified requirements

1 Scope

This document sets out guidelines for checking conformity with quantifiable characteristics using the test or measurement result and its associated measurement uncertainty.

This document is applicable whenever the uncertainty may be quantified according to the principles laid down in ISO/IEC Guide-98-3 (GUM). The term uncertainty is thus a descriptor for all elements of variation in the measurement result, including uncertainty due to sampling.

This document does not give rules for how to act when an inconclusive result of a conformity test has been obtained.

NOTE There are not limitations on the nature of the entity subject to the requirements nor on the quantifiable characteristic. Examples of entities together with quantifiable characteristics are given in Table A.1.

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 3534-1, *Statistics — Vocabulary and symbols — Part 1: General statistical terms and terms used in probability*

ISO 3534-2, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-1, ISO 3534-2 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
limiting values
specification limits
L
specified values of the characteristic giving upper and/or lower bounds of the permissible values

[SOURCE: ISO 3534-2:2006, 3.1.5]

3.2
lower specification limit
L_{SL}
lower bound of the permissible values of the characteristic

3.3
upper specification limit
U_{SL}
upper bound of the permissible values of the characteristic

3.4
conformity assessment
systematic evaluation by means of testing of the extent to which a product, process or service does or does not fulfil specified requirements

3.5
region of permissible values
interval or intervals of all permissible values of the characteristic

Note 1 to entry: Unless otherwise stated in the specification, the limiting values belong to the region of permissible values.

3.6
region of non-permissible values
interval or intervals of all values of the characteristic that are not permissible

Note 1 to entry: Figure 1 displays various possibilities for the partitioning of the region of possible values of the characteristic in regions of permissible and non-permissible values.

3.7
uncertainty interval
interval derived from the actual measurement of the characteristic and its uncertainty, covering the values that could reasonably be attributed to this characteristic at a given probability

Note 1 to entry: An uncertainty interval may be the symmetric interval around the measurement result as defined in ISO/IEC Guide 98-3:2008, 6.2.1.

Note 2 to entry: When the uncertainty has been obtained only by Type A evaluations of uncertainty components, the uncertainty interval may be in the form of a confidence interval for the value of the characteristic (see e.g. ISO 3534-1:2006, 2.57 and ISO/IEC Guide 98-3:2008, G.3).

3.8
two-sided confidence interval
when T_1 and T_2 are two functions of the observed values such that, θ being a population parameter to be estimated, the probability $P_r(T_1 \leq \theta \leq T_2)$ is at least equal to $(1 - \alpha)$ [where $(1 - \alpha)$ is a fixed number, positive and less than 1], the interval between T_1 and T_2 is a two-sided $(1 - \alpha)$ confidence interval for θ

[SOURCE: ISO/IEC Guide 98-3:2008, C.2.27]

3.9
confidence level
the value $(1 - \alpha)$ of the probability associated with a confidence interval or a statistical coverage interval

[SOURCE: ISO/IEC Guide 98-3:2008, C.2.29]

4 Specification of recommendations

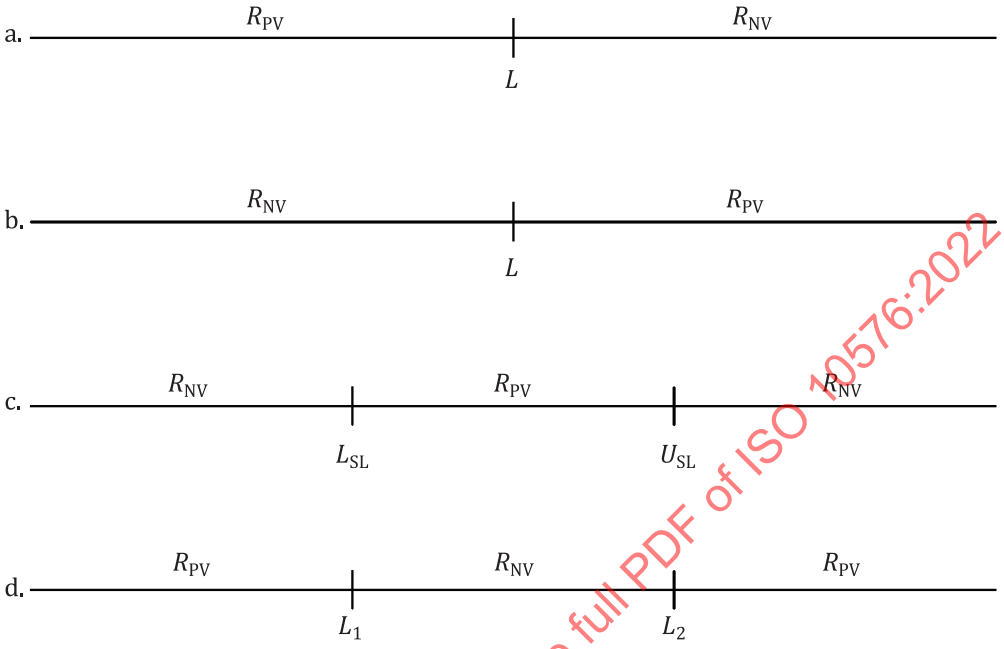
4.1 Recommendations for definition of limiting values

4.1.1 The entity should be clearly and unambiguously specified.

4.1.2 The quantifiable characteristic of the entity should be clearly and unambiguously specified. The value of the characteristic should be determined by means of a measurement or test procedure that enables an assessment of the measurement uncertainty to be made. Examples of entities and their quantifiable characteristics are given in Annex A.

4.1.3 The measurement or test procedure should be a standardized or validated procedure.

4.1.4 The measurement uncertainty should neither explicitly nor implicitly be referred to in the designation of the limiting values.



NOTE R_{PV} denotes region of permissible values while R_{NV} denotes region of non-permissible values. The specification limits are denoted L, L_{SL}, U_{SL}, L_1 and L_2.

Figure 1 — Division of the domain for the characteristic

4.2 Reporting of limiting values

The reporting of limiting values should be the result of the description given in 4.1.1 and 4.1.2.

The range of permissible values of a quantifiable characteristic may be limited to only one side or to both sides. Limits are therefore of two kinds:

— double limits, consisting of an upper *and* a lower limit;

— single limit, i.e. either an upper limit *or* a lower limit.

The possible configuration of limits is illustrated in Figure 1.

EXAMPLE 1 Double limits

For a single item in the form of a barrel of motor oil (i.e. the entity) the requirements for the kinematic viscosity of the oil (i.e. the characteristic) could be

the kinematic viscosity should be not less than $0{,}5 \times 10^{-5}$ m^2/s and not greater than $1{,}0 \times 10^{-5}$ m^2/s.

EXAMPLE 2 Double limits

For one lot of bottles with frying oil (i.e. the entity) the requirements for the average boiling point at the atmospheric pressure of 101,6 kPa for the oil in the bottles (i.e. the characteristic) could be

the average boiling point should be within the interval 105,0 °C to 115,0 °C.

EXAMPLE 3 Single upper limit

For a shipment of crude oil (i.e. the entity) the requirements for the sulfur mass fraction (i.e. the characteristic) in the bulk could be

the sulfur mass fraction should be no greater than 2 %.

EXAMPLE 4 Single upper limit

For an individual (i.e. the entity) the requirements for the concentration of lead in blood (i.e. the characteristic) could be

the concentration of lead should be no greater than 0,97 µmol/l.

EXAMPLE 5 Single lower limit

For a lot of bitumen (i.e. the entity) the requirements for the solubility of the bitumen in kerosene at 20 °C (i.e. the characteristic) could be

the solubility of the bitumen in kerosene at 20 °C should be not less than a mass fraction of 99 %.

EXAMPLE 6 Single upper limit

For a shipment of apples (i.e. the entity) the requirements for mass fraction of the apples infected with pests (i.e. the characteristic) could be

the mass fraction of apples infected with pests should be less than 0,2 %.

Due to the variation of the mass of the individual apples, the mass fraction of infected apples will usually be different from the number fraction of infected apples.

NOTE In many cases (e.g. in the environmental field), an additional implied limit such as 0 %, 0,0 kg/l and 100 % can be ignored when considering a single limit because they are theoretical and/or physical limits and therefore need not be specified.

5 Uncertainty of results

5.1 General

When comparing a measurement result with the limiting values, it is necessary to take into consideration the measurement uncertainty of the result. The uncertainty should be determined according to the provisions of ISO/IEC Guide 98-3. ISO 5725-1 to ISO 5725-6, may also be consulted to help identify some of the components of uncertainty. Examples are shown in Annex B.

NOTE This discussion implies that the contributions to the uncertainty from all stages in the measurement procedure is taken into consideration and also includes any uncertainty due to sampling.

5.2 Reporting the measurement results and the measurement uncertainty

The measured value of the characteristic of interest and the measurement uncertainty should be reported; the measurement uncertainty should be reported as an interval. When this interval is a confidence interval, the confidence level $(1 - \alpha)$ should be reported together with the interval (see ISO 3534-1). Otherwise the coverage factor of the uncertainty interval should be reported (see ISO/IEC Guide 98-3:2008, 6.2.1).

6 Assessing conformity to requirements

6.1 General

A conformity test is a systematic examination (by means of measurement) of whether or not the entity fulfils the specified requirements.

The objective of the conformity assessment is to provide confidence that the entity does or does not fulfil the specified requirements.

This document recommends that the conformity assessment be performed as a two-stage procedure. In the cases where a two-stage procedure either cannot be performed or for other reasons should not be performed, a one-stage procedure is provided.

When a two-stage procedure is performed, there should be appropriate procedures to evaluate the consistency of the measurement results from the two stages.

NOTE The advantage of the two-stage procedure over the one-stage procedure is the higher probability of declaring conformity for entities with permissible values of the quantity of interest, which are close to the limiting value(s). The disadvantage is a slightly higher probability of declaring conformity for entities with non-permissible value(s) of the quantity of interest, which are close to the limiting values. If this increased probability in declaring conformity for non-conforming entities cannot be accepted, a one-stage procedure is provided.

6.2 The two-stage conformity assessment

6.2.1 Stage 1

Perform the measurement procedure and estimate the measurement uncertainty of the result.

Conformity to the requirements may be assured if, and only if, the uncertainty interval is inside the region of permissible values.

The second stage of the test should be performed if, and only if, the uncertainty interval calculated after the first stage includes a specification limit.

6.2.2 Stage 2

Perform the measurement procedure once more and determine an appropriate combination of the two measurement results to form the final measurement result together with the uncertainty of that result.

Conformity to the requirements may be assured if, and only if, the uncertainty interval of the final measurement result is inside the region of permissible values.

If conformity is assured, either after the first or after the second stage, the statement given in 7.2 may be asserted.

NOTE 1 The uncertainty interval is also considered to be inside the region of permissible values when one of the limits of the uncertainty interval coincides with a limiting value of the specification.

If the uncertainty interval is entirely included in the region of non-permissible values, either after the first or after the second stage, then non-conformity with the requirements may be assured and the statement in 7.3 can be asserted.

NOTE 2 The uncertainty interval is also considered to be inside the region of non-permissible values when one of the limits of the uncertainty interval coincides with a limiting value of the specification.

When the uncertainty interval determined after stage 2 includes a specification limit, the result of the conformity assessment is inconclusive, and the statement given in 7.4 may be asserted.

NOTE 3 The measurement procedures used in the two stages need not be identical. The appropriate combination of the results from the first and the second stage referred to in stage 2 above also includes situations where e.g., only the result from stage 2 is used as the final measurement result.

Figure 2 displays a flow diagram for the two-stage conformity assessment.

6.3 The one-stage conformity assessment

Perform the measurement procedure and calculate the measurement uncertainty of the result.

Conformity to the requirements may be assured if, and only if, the uncertainty interval of the measurement result is inside the region of permissible values.

NOTE 1 The uncertainty interval is also considered to be inside the region of permissible values when one of the limits of the uncertainty interval coincides with a limiting value of the specification.

If the uncertainty interval of the measurement result is entirely included in the region of non-permissible values, then non-conformity with the requirements can be declared and the statement in 7.3 may be asserted.

NOTE 2 The uncertainty interval is also considered to be inside the region of non-permissible values when one of the limits of the uncertainty interval coincides with a limiting value of the specification.

When the uncertainty interval includes a specification limit, the result of the conformity assessment is inconclusive, and the statement given in 7.4 may be asserted.

6.4 The uncertainty interval given in the form of a confidence interval

The provisions in this subclause refer to situations where the uncertainty interval is given in the form of a confidence interval with confidence level $(1 - \alpha)$ (see 5.2). When the specification is given in terms of a single specification limit (case a. or case b. in Figure 1), the probability of an erroneous declaration of conformity is at most $\alpha/2$ for the one-stage procedure and at most α for the two-stage procedure from the Bonferroni inequality. In the case with double limits (case c. or d. in Figure 1), the probability of an erroneous declaration of conformity depends on the average length of the confidence interval. However, when the average length is only a small fraction of the difference between the specification limits, the above expression for the probability of an erroneous declaration of conformity may still be used.

When the measurement uncertainty can be assumed to be known (i.e. the uncertainty is not calculated from the observations), the probability of declaring conformity with the requirements can be calculated together with the probability of obtaining an inconclusive result from the conformity assessment.

6.5 Inconclusive result of the conformity assessment

Especially when the value of the characteristic is near a specification limit, there is a large probability that the result of the conformity assessment will be inconclusive. This is in principle undesirable but is inevitable if a declaration of conformity with the requirements should justify the assertion of the statement in 7.2.

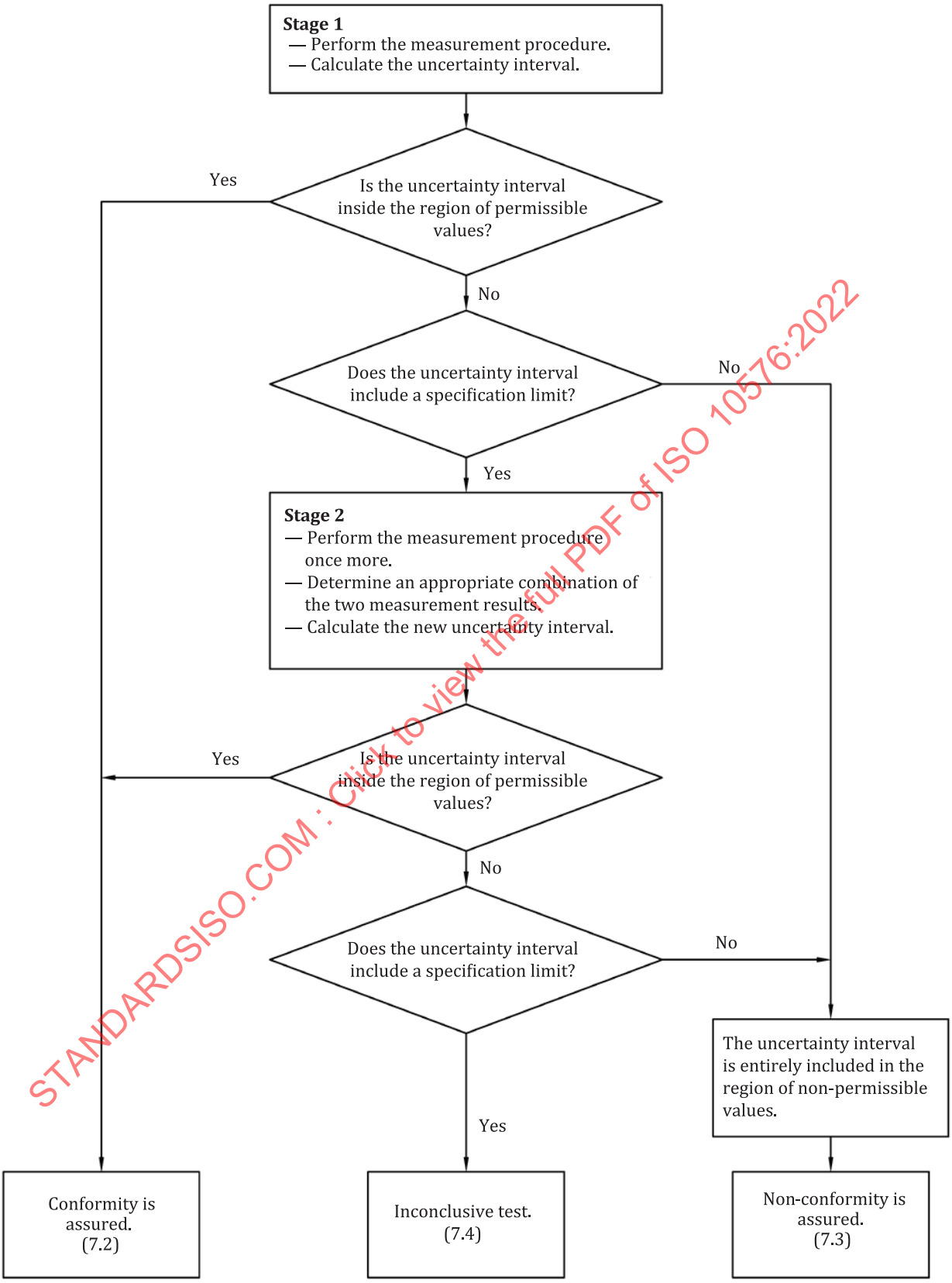


Figure 2 — Flow diagram for the two-stage procedure

7 Reporting the result of the conformity assessment

7.1 General

Due to the variability in measurement, an assertion based upon the measurements may be wrong. The design of the measurement procedure and the test procedure should therefore take this into account in the reporting of a conformity assessment.

When reporting the result of a conformity assessment, the qualitative expressions for assurance of conformity, non-conformity or an inconclusive test given in 7.2, 7.3 and 7.4 should be supplemented with all the evidence which supports the qualitative expression used.

7.2 Assurance of conformity

Whenever the uncertainty interval of the measurement result lies inside the region of permissible values (see 6.1 and 6.2), conformity may be assured.

The assurance of conformity must have the following wording:

The conformity assessment has demonstrated that the value of the characteristic is in conformity with the requirements.

7.3 Assurance of non-conformity

Whenever the uncertainty interval of the measurement result is inside the region of non-permissible values (see 6.1 and 6.2), non-conformity may be assured.

The assurance of non-conformity must have the following wording:

The conformity assessment has demonstrated that the value of the characteristic is not in conformity with the requirements.

7.4 Inconclusive result

Whenever neither conformity nor non-conformity with the requirements can be assured in accordance with 6.1 or 6.2, the result of the conformity assessment is inconclusive.

The report of an inconclusive test result must have the following wording:

The conformity assessment has not been able to demonstrate that the value of the characteristic is or is not in conformity with the requirements.

Annex A
(informative)

Examples of entities and quantifiable characteristics

Table A.1 — Examples of entities together with quantifiable characteristics

Entity	Quantifiable characteristic of entity			
	Item characteristic	**Average**	**Homogeneity**	**Relative frequency**
Distinguishable item or individual	×	—	×	—
{weight for a balance}	{mass}	—	—	—
Group of distinguishable items (batch or population)	—	×	×	×
{lot of bags of sugar}	—	{the average mass per bag}	{the standard deviation of the mass of bags}	{the percentage of bags with conforming masses}
Process	—	×	×	×
{production of bottles}	—	{the average volume per bottle produced}	{the standard deviation of the volume of the bottles produced}	{the percentage of produced bottles with conforming volumes}
Lot of bulk material (particulate material, liquid or gas)	—	×	×	×
{lot of dolomite}		{the mass fraction of asbestos fibres}	{the standard deviation of the mass fraction of asbestos between specified sampling units}	{the mass fraction of asbestos fibres with conforming length}
Service	—	×	×	×
{treatment of a specific disease}	—	{the average waiting time from the reporting of the disease until the start of the treatment}	{the standard deviation of the waiting time from the reporting of the disease until the start of the treatment}	{the percentage of waiting times for the start of the treatment with conforming length}

NOTE 1 The symbol "×" in the cell indicates that the characteristic may be considered for the entity in question. Specific examples are given in accolades { }.

NOTE 2 The contents of this table should not be considered exhaustive.

Annex B
(informative)

Examples

B.1 General

The following examples cover only some of the combinations of the entities and quantifiable characteristics given in Table A.1. The examples do not represent any specific important combinations of entity and characteristic of interest. All the examples should be seen as illustrative only and do not necessarily represent the procedures of any regulatory body.

B.2 Example 1

In a series of fine turned steel shafts, nominal dimensions Ø 24 mm × 150 mm, the specification limits for the diameter (two point diameter) of each shaft is L_{SL}= 23,9 mm and U_{SL}= 24,0 mm. The entity is thus a shaft and the characteristic is the shaft diameter.

The measurements are performed using an analogue external micrometer with flat measuring anvils, a measuring range of 0 mm to 25 mm with a Vernier scale interval division of 10^{-3} mm. The standard uncertainty of measurement, u_c = 3,79 × 10^{-3} mm, is calculated from a number of contributors (see ISO 14253-2:2011, A.2). For economic reasons a one-stage conformity assessment was performed for each of the shafts in the series instead of a two-stage test. The uncertainty intervals were calculated in accordance with ISO Guide 98-3:2008, 6.2.1, using the coverage factor k = 2. The uncertainty intervals around the measurements of three shafts were (23,857 ± 0,007 6) mm; (23,907 ± 0,007 6) mm and (23,962 ± 0,007 6) mm. In accordance with 6.3, the first shaft is declared to be non-conforming and the third shaft is declared to be conforming to the requirements while the conformity assessment of the second shaft has given an inconclusive result.

B.3 Example 2

According to a list of limiting values, the concentration of lead in blood for individuals should not exceed 0,97 µmol/l. The entity is thus the blood of an individual. The characteristic is per definition the concentration of trace metal in the blood at the time the blood sample is taken. When a two-stage procedure is used the blood sample is divided into two subsamples and the second sample is only measured if the uncertainty interval after the first stage contains a limiting value (see 6.2). The measurements are performed with a standard measurement procedure which gives a result with standard uncertainty σ_Y = 0,048 µmol/l[7][8]. The uncertainty interval of a measurement result can be expressed in the form of a (1 − α) confidence interval for the value of the characteristic[10][11]. When n independent measurements each with the uncertainty σ_Y are performed and the arithmetic mean of the measurements is Y_1 then the confidence interval is given as:

$$Y_1 \pm \frac{z_{1-\alpha/2}\sigma_Y}{\sqrt{n}}$$

where $z_{1-\alpha/2}$ is the 1 − α/2 quantile of the standard normal distribution[1].

The concentration of Pb in the blood for a particular individual is measured. The individual is only exposed to lead through daily food intake and the exhaust emissions from motor vehicles. The estimate of the Pb concentration from the measurement of the first subsample (n = 1) of blood is calculated as Y_1 = 0,60 µmol/l. The uncertainty interval given in the form of a 0,95 confidence interval for the blood

concentration of Pb is 0,504 µmol/l to 0,693 µmol/l. Since this interval is entirely included in the region of conformity, then, in accordance with 6.3, conformity with the requirements is declared.

The Pb concentration for another individual with a supplementary exposure to lead coming from his daily work is also measured. The measurement result from the first subsample (n = 1) is Y_1 = 1,06 µmol/l and the corresponding 0,95 confidence interval for the Pb concentration is 0,96 µmol/l to 1,15 µmol/l. Since this interval includes the limiting value, the second subsample is measured (n = 1). This measurement result is 1,00 µmol/l. The measurements from the two stages are combined to Y_* = (1,06 + 1,00)/2 µmol/l = 1,03 µmol/l. The confidence interval for the Pb concentration based on the arithmetic mean of the two estimates is calculated from the formula given above (n = 2) resulting in the interval 0,96 µmol/l to 1,10 µmol/l. The limiting value is inside this interval. Thus, it cannot be concluded that the concentration of Pb is in conformity with the requirements. Correspondingly, it cannot be concluded that the Pb concentration is not in conformity with the requirements. In accordance with 6.3, the result from the two conformity assessments is therefore inconclusive.

It should be emphasised that the procedure of performing a conformity assessment for the concentration of lead in human blood given above is not equivalent to the standard procedure currently used.

It was assumed in this example that the measurements are statistically independent of one another. In practice, measurements taken in the same laboratory over a short time period are likely to be correlated. In the next example the effect of the correlation of results is illustrated.

B.4 Example 3

It is common to test denatured alcohols to verify that the product contains an adequate amount of the denaturing agent. Suppose, for example, that the denaturing agent is propan-2-ol (isopropyl alcohol abbreviated IPA herein) and IPA is required to be present in the concentration of at least 30,0 mg/g. From previous testing, the lab-to-lab standard deviation of the analytical method is σ_L = 1,2 mg/g and the repeatability standard deviation is σ_r = 0,9 mg/g. From ISO 5725-6:1994 4.2.3, the standard deviation of the average of n measurements taken in a short period of time is

$$\sigma = \sqrt{\sigma_L^2 + \sigma_r^2 / n}$$

Suppose the first test result is 32,5 mg/g, then the lower boundary for a 0,95 confidence interval is $Y_1 - z_{0,975}\ \sigma = 32{,}5 - 1{,}96 \times 1{,}5 = 29{,}6\ \text{mg/g}$ and the result is inconclusive, since the confidence interval includes 30,0 mg/g. In the equation for the lower confidence boundary, $z_{0,975}$ is the 97,5$^{\text{th}}$ percentile of a standard normal distribution and σ is calculated by substitution in the equation above with n=1. Suppose the second test result is 33,3 mg/g. Y_2 is the average of the two readings and the lower boundary for the confidence interval is $Y_2 - z_{0,975}\ \sigma = 30{,}2\ \text{mg/g}$. Since the lower boundary does not include 30,0, the sample is shown to be in conformance with the 30 mg/g requirement.

One of the purposes of this example was to illustrate the case of having correlated results. When measurements are positively correlated (which will typically be the case), the reduction in variation of the mean with additional replicates is much less than if the results are independent of one another. The correlation comes about because all test results are from the same laboratory, often within a very narrow timeframe under something very close to repeatability conditions. In this example, with more and more replicates, the standard deviation asymptotes to the lab-to-lab standard deviation 1,2 mg/g (not zero) and the reduction in uncertainty is disappointingly small with additional test results. For many naïve practitioners, it will be assumed that the values are independent of one another. Further the user will often take the short-term method variation to be the only component of variance and will effectively only take the repeatability standard deviation into account and not think to include the lab-to-lab variability. The effect on the estimated uncertainty associated with different assumptions is illustrated in Figure B.1. The solid line shows the actual reduction in uncertainty with increased testing within the same lab over a short time period. The two dashed lines show the reduction that would result if the testing were independent. It is common to assume independence, but more difficult to bring it about. Assuming independence will often give a significant underestimate of the uncertainty associated with the mean of replicated results. One approach to reducing the correlation between