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

**Part 1:
General principles**

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

Partie 1: Principes généraux



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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.

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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 10576-1 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 6, *Measurement methods and results*.

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Introduction

Conformity testing 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, 1996). 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 testing 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 minimize 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 whenever an entity has been declared to be conforming, this status should not be altered by subsequent measurements on the entity, even using more precise measurements (e.g. a better measurement method or technology). Or, in terms of risks, the risk of (erroneously) declaring a non-conforming entity to be conforming shall 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 will in general decrease this risk.

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

In this part of ISO 10576, this issue is addressed in respect of the construction of specifications and the testing of output from production or service processes for conformity and non-conformity with specifications.

The problems of how to determine the relevant components of uncertainty and how to estimate them will be addressed in a future ISO 10576-2.

Because of the apparent similarity to acceptance sampling procedures, it is sometimes seen that acceptance sampling plans are used in conformity testing activities. Acceptance sampling and conformity testing 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]).

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

Part 1: General principles

1 Scope

This part of ISO 10576 sets out guidelines:

- a) for drafting requirements that may be formulated as limiting values for a quantifiable characteristic;
- b) for checking conformity to such requirements when the test or measurement result is subject to uncertainty.

This part of ISO 10576 is applicable whenever the uncertainty may be quantified according to the principles laid down in GUM. The term uncertainty is thus a descriptor for all elements of variation in the measurement result, including uncertainty due to sampling.

It is outside the scope of this part of ISO 10576 to give rules for how to act when an inconclusive result of a conformity test has been obtained.

NOTE Neither on the nature of the entity subject to the requirements nor on the quantifiable characteristic are there limitations. Examples of entities together with quantifiable characteristics are given in Table A.1.

2 Normative references

The following referenced documents are indispensable for the application 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 3534-1:1993, *Statistics — Vocabulary and symbols — Part 1: Probability and general statistical terms*

ISO 3534-2:1993, *Statistics — Vocabulary and symbols — Part 2: Statistical quality control*

ISO 5725-1:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

ISO 5725-2:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

ISO 5725-3:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 3: Intermediate measures of the precision of a standard measurement method*

ISO 5725-4:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 4: Basic methods for the determination of the trueness of a standard measurement method*

ISO 5725-5:1998, *Accuracy (trueness and precision) of measurement methods and results — Part 5: Alternative methods for the determination of the precision of a standard measurement method*

ISO 5725-6:1994, *Accuracy (trueness and precision) of measurement methods and results — Part 6: Use in practice of accuracy values*

Guide to the expression of uncertainty in measurement (GUM):1993¹⁾, BIPM/IEC/IFCC/ISO/IUPAC/IUPAP/OIML

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.

3.1

limiting values

specification limits

L

specified values of the characteristic giving upper and/or lower bounds of the permissible values

[ISO 3534-2:1993, 1.4.3]

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 test

systematic evaluation by means of testing of the extent to which a product, process or service fulfils specified requirements

3.5

region of permissible values

interval or intervals of all permissible values of the characteristic

NOTE 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 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.

1) Published in 1993 but corrected and reprinted in 1995.

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

NOTE 1 An uncertainty interval may be the symmetric interval around the measurement result as defined in 6.2.1 of GUM:1993.

NOTE 2 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., 2.57 of ISO 3534-1:1993 and G.3 of GUM:1993).

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

[ISO 3534-1:1993, 2.57]

3.9**confidence coefficient****confidence level**

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

[ISO 3534-1:1993, 2.59]

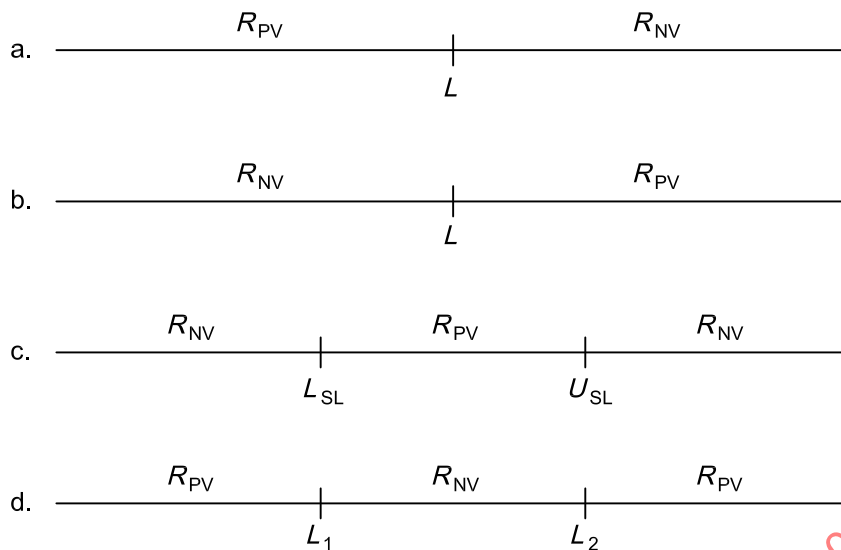
4 Specification of requirements**4.1 Requirements for definition of limiting values**

4.1.1 The entity shall be clearly and unambiguously specified.

4.1.2 The quantifiable characteristic of the entity shall be clearly and unambiguously specified. The value of the characteristic shall be determined by means of a measurement or test procedure that enables an assessment of the uncertainty of the measurement to be made.

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

4.1.4 The uncertainty of the measurement shall 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 shall be the result of the drafting 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.

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 shall be not less than $0,5 \times 10^{-5} \text{ m}^2/\text{s}$ and no greater than $1,00 \times 10^{-5} \text{ m}^2/\text{s}$.

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 shall 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 shall 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 shall be no greater than 0,96 $\mu\text{mol/l}$.

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 shall 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 shall 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 necessarily to be specified.

5 Uncertainty of results

5.1 General

When comparing a measurement or test result with the limiting values, it is necessary to take into consideration the uncertainty of the measurement result. The uncertainty shall be determined according to the provisions of the GUM. ISO 5725, parts 1 to 6, may also be consulted to help identify some of the components of uncertainty.

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

5.2 Reporting the uncertainty of the measurement result

The measurement result of the measured characteristic of interest and the uncertainty of the measurement shall be reported; the uncertainty of the measurement shall be reported as an uncertainty interval. When this interval is a confidence interval, the confidence level ($1 - \alpha$) shall be reported together with the interval (see 2.57 and 2.59 of ISO 3534-1:1993). Otherwise the coverage factor of the uncertainty interval shall be reported (see 6.2.1 of GUM:1993).

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 test is to provide confidence that the entity fulfils the specified requirements.

This part of ISO 10576 recommends that the conformity test 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 shall 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 considerably 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 values 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 should be provided.

6.2 The two-stage conformity test

6.2.1 Stage 1

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

The second stage of the test shall 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 may be 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 of the measurement result 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 test 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 test.

6.3 The one-stage conformity test

Perform the measurement procedure and calculate the uncertainty of the measurement 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 test 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 $\alpha + \alpha^2/2$ for the two-stage procedure. In the case with two specification 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 uncertainty of the measurements can be assumed to be completely 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 test.

NOTE Examples will be provided in a future ISO 10576-2.

6.5 Inconclusive result of the conformity test

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

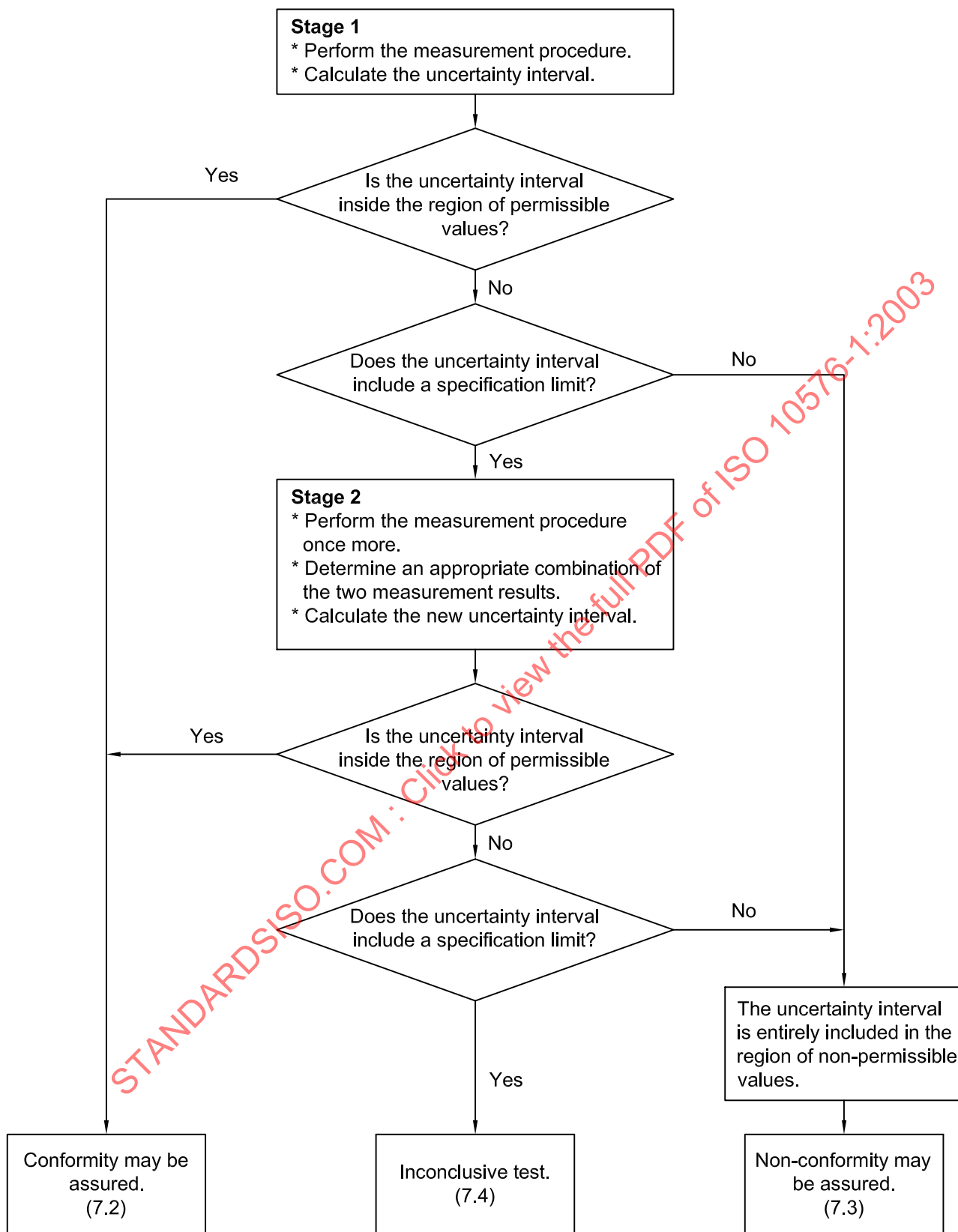


Figure 2 — Flow diagram for the two-stage procedure

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 shall therefore take this into account in the reporting of a conformity test.

When reporting the result of a conformity test, the qualitative expressions for assurance of conformity, non-conformity or an inconclusive test given in 7.2, 7.3 and 7.4 shall 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 is inside the region of permissible values (see 6.1 and 6.2), conformity may be assured.

The assurance of conformity shall have the following wording:

The conformity test has demonstrated beyond any reasonable doubt 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 shall have the following wording:

The conformity test has demonstrated beyond any reasonable doubt 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 test is inconclusive.

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

The conformity test has not been able to demonstrate beyond any reasonable doubt 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}
The symbol "×" in the cell indicates that the characteristic may be considered for the entity in question. Specific examples are given in accolades { }.				
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.

B.2 Example 1

In a series of fine turned steel shafts, nominal dimensions $\varnothing 25 \text{ mm} \times 150 \text{ mm}$, the specification limits for the diameter (two point diameter) of each shaft is $L_{SL} = 24,9 \text{ mm}$ and $U_{SL} = 25,0 \text{ mm}$. 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 to 25 mm with a Vernier scale interval of 10^{-3} mm . The standard uncertainty of measurement, $u_c = 3,79 \times 10^{-3} \text{ mm}$, is calculated from a number of contributors (see A.2 of ISO/TS 14253-2:1999). For economic reasons a one-stage conformity test was performed for each of the shafts in the series instead of a two-stage test. The uncertainty intervals were calculated in accordance with 6.2.1 of GUM:1993, using the coverage factor $k = 2$. The uncertainty intervals around the measurements of three shafts were $(24,857 \pm 0,0076) \text{ mm}$; $(24,907 \pm 0,0076) \text{ mm}$ and $(24,962 \pm 0,0076) \text{ mm}$. 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 test 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 shall not exceed $0,97 \mu\text{mol/l}$. 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 operates with an uncertainty of $\sigma_Y = 0,048 \mu\text{mol/l}$ ^[7,8]. The uncertainty interval of a measurement can be expressed in the form of a $(1 - \alpha)$ 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

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

where $u_{1-\alpha/2}$ is the $1 - \alpha/2$ 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 $Y_1 0,60 \mu\text{mol/l}$. The uncertainty interval given in the form of a 0,95 confidence interval for w is $0,504 \mu\text{mol/l}$ to $0,693 \mu\text{mol/l}$. Since this interval is entirely included in the region of conformity, then, in accordance with 6.3, conformity with the requirements is declared.