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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.

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

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):*1993[1)], 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 $P_r(T_1 \leqslant \theta \leqslant T_2)$ 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

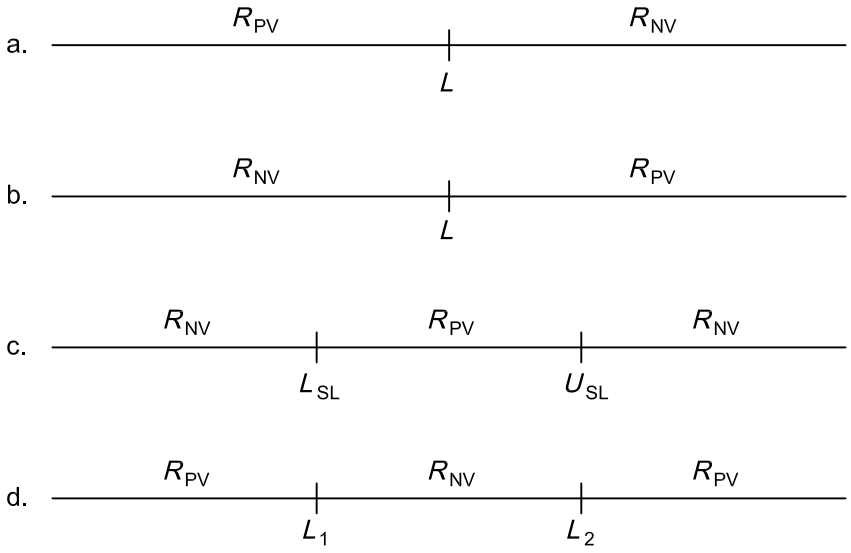
4.1 Requirements for definition of limiting values

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 $0{,}5 \times 10^{-5}$ m^2/s and no greater than $1{,}00 \times 10^{-5}$ 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 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 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 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.