# INTERNATIONAL STANDARD

# ISO 10576-1

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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.