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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.

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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.

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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

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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.

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