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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Contents

Page

Foreword

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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.

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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]).

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.

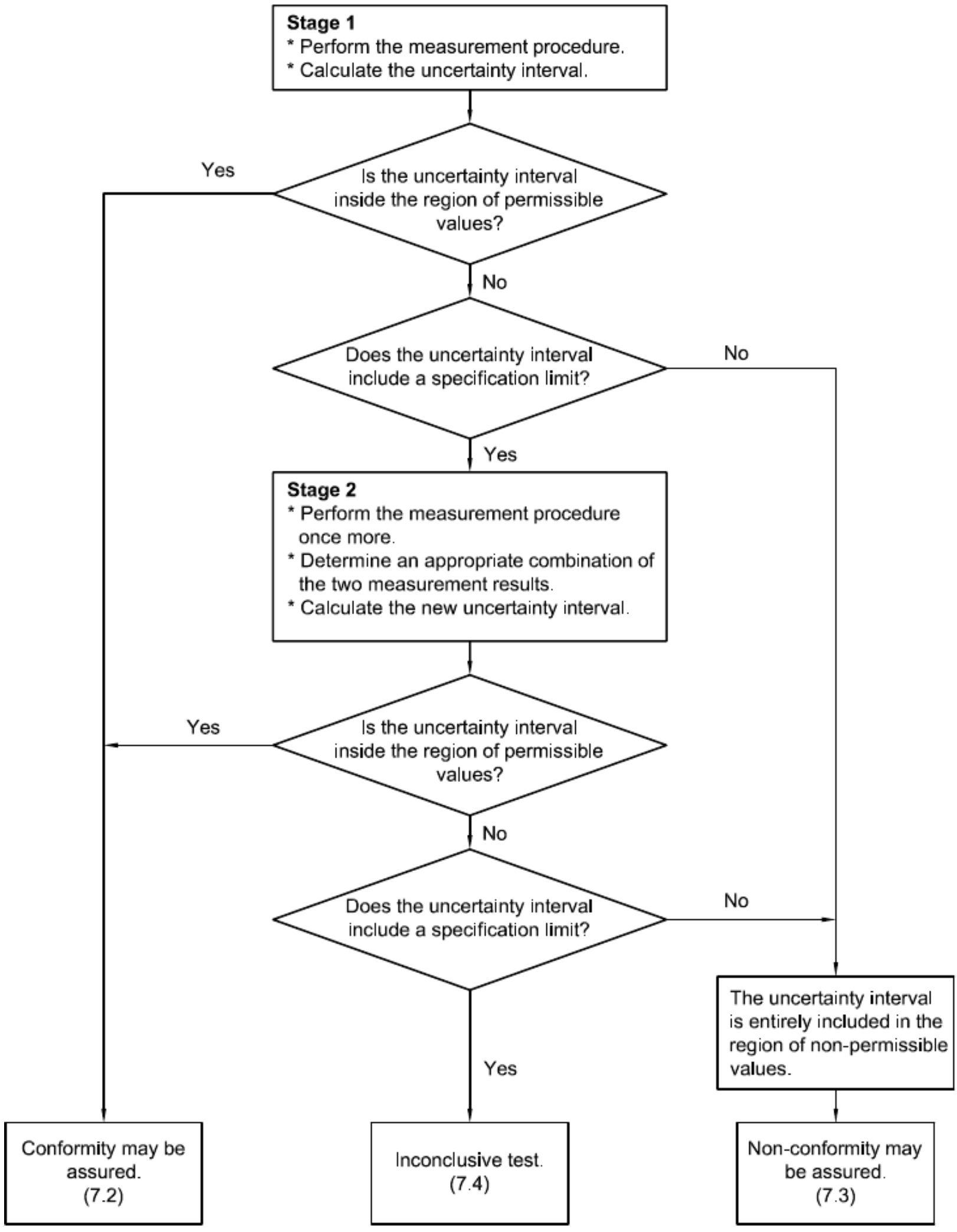

Figure 2 — Flow diagram for the two-stage procedure

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