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Water quality — Guidance for establishing the equivalency of results

Qualité de l'eau — Lignes directrices pour la création de l'équivalence des résultats

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Contents

Page

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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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/TS 16489 was prepared by Technical Committee ISO/TC 147, *Water quality*, Subcommittee SC 2, *Physical, chemical and biochemical methods*.

Introduction

The methods referred to in this Technical Specification can comprise a standard or reference method, the results of which are to be compared with results generated by an alternative, perhaps more simple, method. Alternatively, a comparison of results produced by an old established method and those produced by a new more modern technique can be undertaken. The methods can be laboratory based or undertaken “on-site” where the samples are taken.

No indication is given to confirm whether either one of the two methods, in terms of bias, is better or worse than the other method, only that the results produced by both methods are considered equivalent or not, in terms of the calculated means, standard deviations and variances. The procedures described are not to be used for, and do not apply to, situations to establish whether two methods can be shown to be equivalent. The procedures apply only to demonstrating equivalency of results.

Since standard deviations and means can vary with concentrations, especially where concentrations vary over several orders of magnitude, the procedures described in Clauses 7 to 9 are only applicable to samples containing a single level of concentration. It would be necessary to repeat the procedures for each concentration level if different concentration levels are encountered, and it is shown that standard deviations and means vary over these concentration levels. It might be that the demonstration of equivalence can only be achieved over relatively small concentration ranges. For multiple concentration levels, the procedures described in Clause 10 might be applicable. In addition, the laboratory will need to show that both methods are suitable and appropriate for the sample matrix and the parameter under investigation, including the level of concentration of the parameter. Also, the experimental data obtained in the comparison of results should reflect the specific application for which equivalence is questioned, as different matrices can lead to different results with the two methods.

Throughout this Technical Specification, it is assumed that results are obtained essentially under repeatability conditions, but it is recognized that this will not always be so. Hence, where appropriate, identical samples are analysed by the same analyst using the same reagents and equipment in a relatively short period of time. Furthermore, a level of confidence of 95 % is assumed. The statistical tests described in this Technical Specification assume that the data to be compared are independent and normally distributed in a Gaussian manner. If they are not, the data might not be suitable for the statistical treatments described and additional data might need to be collected.

The power of the statistical test is greatly enhanced when sufficient data are available for comparisons; i.e. when the numbers of degrees of freedom are available to enable a meaningful interpretation to be made. However, it is recognized that a statistically significant difference might not necessarily infer an important or meaningful difference, and a personal judgement should be made on whether a statistically significant difference is important or meaningful and relevant. Alternatively, a statistical test might not be sufficiently powerful to be able to detect a difference that from a practical point of view could be regarded as important or meaningful.

To aid the analyst, advice is provided as to which clause (and corresponding annex) is applicable to the circumstances surrounding the data that have been generated. It is recognized that when results are compared they can have been generated under a variety of different conditions.

Water quality — Guidance for establishing the equivalency of results

1 Scope

This Technical Specification describes statistical procedures to test the equivalency of results obtained by two different analytical methods used in the analysis of waters. This Technical Specification is not applicable for establishing whether two methods can be shown to be equivalent. The procedures given in this Technical Specification are only applicable to demonstrating the equivalency of results.

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 5725-2, *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*

NOTE A practical guidance document to assist in the use of ISO 5725-2 has been published: see ISO/TR 22971.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply:

3.1
precision
closeness of agreement between independent test results obtained under repeatability conditions

NOTE 1 Precision depends only on the distribution of random errors and does not relate to the true, specified or accepted value.

NOTE 2 Measurement of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results. Less precision is reflected by a larger standard deviation.

NOTE 3 “Independent test results” means results obtained in a manner not influenced by any previous result on the same sample. Quantitative measurements of precision depend critically on stipulated conditions.

3.2
repeatability conditions
conditions where independent test results are obtained with the same method on identical test samples in the same laboratory, by the same operator, using the same reagents and equipment within short intervals of time

3.3
analytical method
unambiguously written procedure describing all details required to carry out the analysis of the determinand or parameter, namely: scope and field of application, principle and/or reactions, definitions, reagents, apparatus, analytical procedures, calculations and presentation of results, performance data and test report