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Statistical methods for use in proficiency testing by interlaboratory comparison

Méthodes statistiques utilisées dans les essais d'aptitude par comparaison interlaboratoires

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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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 6, *Measurement methods and results*.

This third edition of ISO 13528 cancels and replaces the second edition (ISO 13528:2015), of which it constitutes an minor revision. The changes are as follows:

— notes have been added to 10.1, 10.4.3 and 10.5.3 to draw attention to additional graphical techniques that can assist in meeting the provisions of 10.1;

— Formulae B.4 and B.8 have been corrected to use s_t^2 instead of w_t^2;

— Formula B.16 has been corrected so that the term inside the square root is always non-negative;

— in Table C.2, the correction factor associated with p = 2 has been corrected to read 0,3994;

— additional literature references to the source of values in Table C.2 have been added to the Bibliography and referenced from Notes 1 and 2 of C.5.2.1;

— font styles (Italic or Roman) have been amended throughout for consistency in formulae.

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0 Introduction

0.1 The purposes of proficiency testing

Proficiency testing involves the use of interlaboratory comparisons to determine the performance of participants (which may be laboratories, inspection bodies, or individuals) for specific tests or measurements, and to monitor their continuing performance. There are a number of typical purposes of proficiency testing, as described in the Introduction to ISO/IEC 17043. These include the evaluation of laboratory performance, the identification of problems in laboratories, establishing effectiveness and comparability of test or measurement methods, the provision of additional confidence to laboratory customers, validation of uncertainty claims, and the education of participating laboratories. The statistical design and analytical techniques applied shall be appropriate for the stated purpose(s).

0.2 Rationale for scoring in proficiency testing schemes

A variety of scoring strategies is available and in use for proficiency testing. Although the detailed calculations differ, most proficiency testing schemes compare the participant's deviation from an assigned value with a numerical criterion which is used to decide whether or not the deviation represents cause for concern. The strategies used for value assignment and for choosing a criterion for assessment of the participant deviations are therefore critical. In particular, it is important to consider whether the assigned value and criterion for assessing deviations should be independent of participant results, or should be derived from the results submitted. In this document, both strategies are provided for. However, attention is drawn to the discussion that will be found in Clauses 7 and 8 of the advantages and disadvantages of choosing assigned values or criteria for assessing deviations that are not derived from the participant results. It will be seen that in general, choosing assigned values and assessment criteria independently of participant results offers advantages. This is particularly the case for the criterion used to assess deviations from the assigned value – such as the standard deviation for proficiency assessment or an allowance for measurement error – for which a consistent choice based on suitability for a particular end use of the measurement results, is especially useful.

0.3 ISO 13528 and ISO/IEC 17043

This document provides support for the implementation of ISO/IEC 17043 particularly, on the requirements for the statistical design, validation of proficiency test items, review of results, and reporting summary statistics. ISO/IEC 17043:2010, Annex B, briefly describes the general statistical methods that are used in proficiency testing schemes. This document is intended to be complementary to ISO/IEC 17043, providing detailed guidance that is lacking in that document on particular statistical methods for proficiency testing.

The definition of proficiency testing in ISO/IEC 17043 is repeated in this document, with the notes that describe different types of proficiency testing and the range of designs that can be used. This document cannot specifically cover all purposes, designs, matrices and measurands. The techniques presented in this document are intended to be broadly applicable, especially for newly established proficiency testing schemes. It is expected that statistical techniques used for a particular proficiency testing scheme will evolve as the scheme matures; and the scores, evaluation criteria, and graphical techniques will be refined to better serve the specific needs of a target group of participants, accreditation bodies, and regulatory authorities.

This document incorporates published guidance for the proficiency testing of chemical analytical laboratories[32] but additionally includes a wider range of procedures to permit use with valid measurement methods and qualitative identifications. The revision of this document contains most of the statistical methods and guidance from the first edition, extended as necessary by the previously referenced documents and the extended scope of ISO/IEC 17043. ISO/IEC 17043 includes proficiency testing for individuals and inspection bodies, including ISO/IEC 17043:2010, Annex B, which includes considerations for qualitative results.

This document includes statistical techniques that are consistent with other International Standards, particularly those of TC69/SC6, notably the ISO 5725 series of standards on Accuracy: trueness and

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precision. The techniques are also intended to reflect other International Standards, where appropriate, and are intended to be consistent with ISO/IEC Guide 98-3 (GUM) and ISO/IEC Guide 99 (VIM).

0.4 Statistical expertise

ISO/IEC 17043 requires that in order to be competent, a proficiency testing provider shall have access to statistical expertise and shall authorize specific personnel to conduct statistical analysis. Neither ISO/IEC 17043 nor this document can specify further what that necessary expertise is. For some applications an advanced degree in statistics is useful, but usually the needs for expertise can be met by individuals with technical expertise in other areas, who are familiar with basic statistical concepts and have experience or training in the common techniques applicable to the analysis of data from proficiency testing schemes. If an individual is responsible for statistical design and/or analysis, it is very important that this person has experience with interlaboratory comparisons, even if that person has an advanced degree in statistics. Conventional advanced statistical training often does not include exercises with interlaboratory comparisons, and the unique causes of measurement error that occur in proficiency testing can seem obscure. The guidance in this document cannot provide all the necessary expertise to consider all applications, and cannot replace the experience gained by working with interlaboratory comparisons.

0.5 Computer software

Computer software that is needed for statistical analysis of proficiency testing data can vary greatly, ranging from simple spread sheet arithmetic for small proficiency testing schemes using known reference values to sophisticated statistical software used for statistical methods reliant on iterative calculations or other advanced numerical methods. Most of the techniques in this document can be accomplished by conventional spread sheet applications, perhaps with customised routines for a particular proficiency testing scheme or analysis; some techniques will require computer applications that are freely available. In all cases, the users are expected to verify the validity and accuracy of their calculations, especially when special routines have been entered by the user. However, even when the techniques in this document are appropriate and correctly implemented by adequate computer applications, they cannot be applied without attention from an individual with technical and statistical expertise that is sufficient to understand the nature of the applications and the statistical assumptions, and to identify and investigate anomalies that can occur in any round of a proficiency testing scheme.

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