INTERNATIONAL STANDARD

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Statistical methods for use in proficiency testing by interlaboratory comparisons

Méthodes statistiques utilisées dans les essais d'aptitude par comparaisons 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.

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 13528 was prepared by Technical Committee ISO/TC 69, *Applications of statistical methods*, Subcommittee SC 6, *Measurement methods and results*.

0 Introduction

0.1 The aims of proficiency testing

Proficiency testing by interlaboratory comparisons is used to determine the performance of individual laboratories for specific tests or measurements, and to monitor the continuing performance of laboratories. The Introduction to ISO/IEC Guide 43-1:1997 should be consulted for a full exposition of the purposes of proficiency testing. In statistical language, the performance of laboratories can be described by three properties: laboratory bias, stability and repeatability. Laboratory bias and repeatability are defined in ISO 3534-1, ISO 3534-2 and ISO 5725-1. The stability of a laboratory's results is measured by intermediate precision as defined in ISO 5725-3.

Laboratory bias may be assessed by tests on reference materials, when these are available, using the procedure described in ISO 5725-4. Otherwise, proficiency testing by interlaboratory comparisons provides a generally available means of obtaining information about laboratory bias, and the use of data from proficiency tests to obtain estimates of laboratory bias is an important aspect of the analysis of such data. However, stability and repeatability will affect data obtained in proficiency tests, so that it is possible for a laboratory to obtain data in a round of a proficiency test which indicate bias that is actually caused by poor stability or poor repeatability. It is therefore important that these aspects of laboratory performance are assessed regularly.

Stability may be assessed by re-testing of retained samples, or by making regular measurements on a reference material or an in-house reference material (a stock of material established by a laboratory to use as private reference material). These techniques are described in ISO 5725-3. Stability may also be assessed by plotting estimates of laboratory bias derived from proficiency tests in control charts. This can provide information about laboratory performance that is not apparent from the examination of the results of individual rounds of proficiency testing schemes, and is another important aspect of the analysis of such data.

Data suitable for assessing repeatability may be generated by tests carried out in the normal course of the work of a laboratory, or by extra tests carried out within a laboratory specifically to assess repeatability. Consequently, the assessment of repeatability is not necessarily an important aspect of proficiency testing, although it is important that laboratories monitor their repeatability in some way. Repeatability may be assessed by plotting ranges of duplicate measurements on a control chart as described in ISO 5725-6.

The flowchart (Figure 1) illustrates how the techniques described in this International Standard are to be applied.

0.2 ISO/IEC Guide 43

ISO/IEC Guide 43-1 describes different types of proficiency testing schemes and gives guidance on the organization and design of proficiency testing schemes. ISO/IEC Guide 43-2 gives guidance on the selection and use of proficiency testing schemes by laboratory accreditation bodies. Those documents should be consulted for detailed information in those areas (the information is not duplicated here). ISO/IEC Guide 43-1 contains an annex that briefly describes the statistical methods that are used in proficiency testing schemes.

This International Standard is complementary to ISO/IEC Guide 43, providing detailed guidance that is lacking in that document on the use of statistical methods in proficiency testing. ISO 13528 is to a large extent based on a harmonized protocol for the proficiency testing of analytical laboratories [1], but is intended for use with all measurement methods.

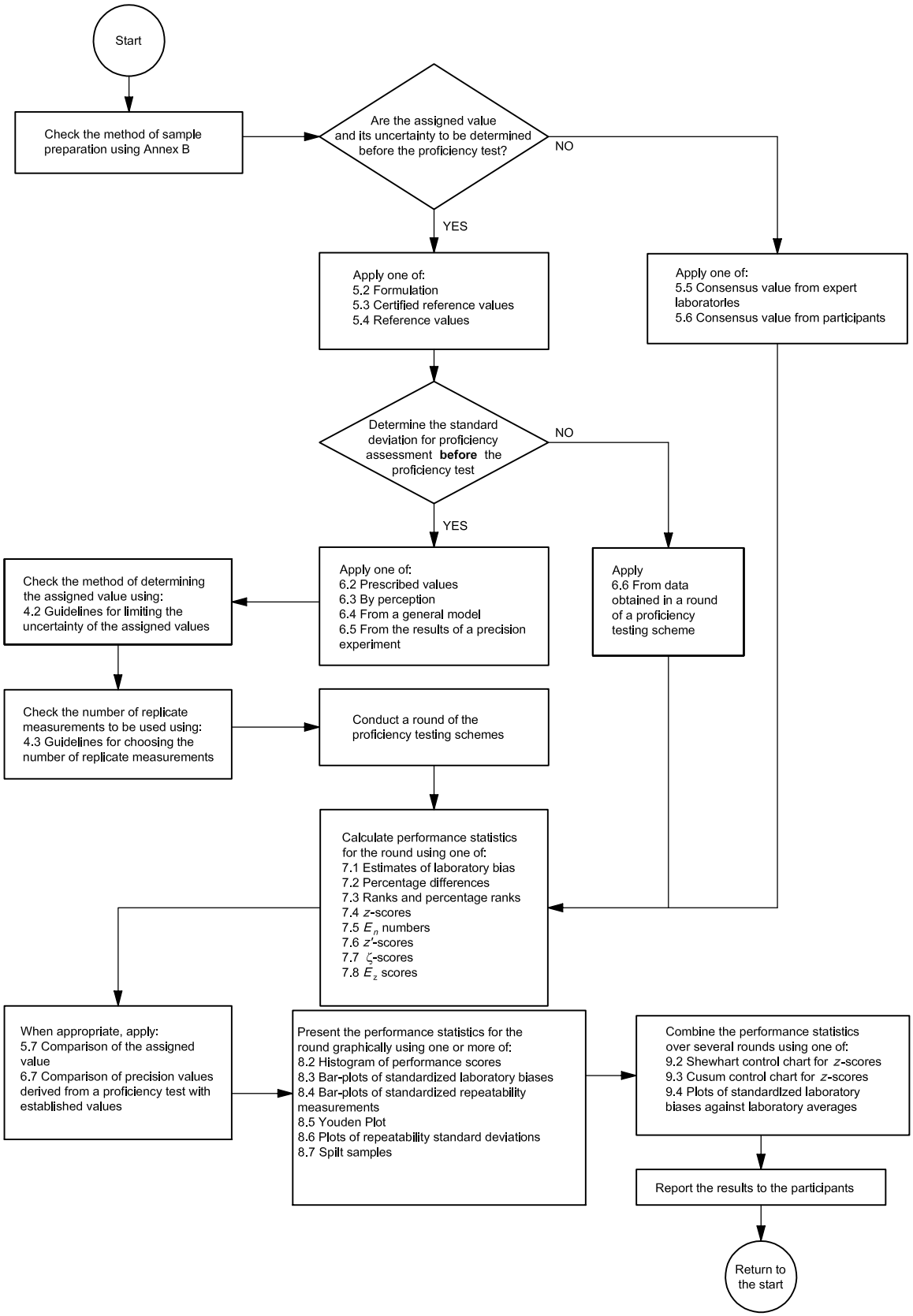

Figure 1 — Flowchart showing the activities requiring the use of statistical methods when operating a proficiency testing scheme

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