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Statistical analysis for evaluating the precision of binary measurement methods and their results

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Foreword

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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).

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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, *Application of statistical methods*, Subcommittee SC 6, *Measurement methods and results*.

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

The documents in the ISO 5725 series define the precision of quantitative measurement methods and their results, and assume that the errors follow normal distributions in their basic models. Also, they provide how to run experiments to evaluate precision measures, such as repeatability and reproducibility. Nowadays, there is also a demand for dealing with qualitative measurement methods and their results, which output binary data, categorical data, etc. However, the ISO 5725 series is not suitable mathematically for analyzing such data.

Several existing studies propose statistical methods for dealing with binary and/or categorical data, but no guidance documents are available so far. Hence, this document summaries various methods to evaluate the precision of binary measurement methods and their results, which are the most essential and frequently used methods for qualitative data.

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Statistical analysis for evaluating the precision of binary measurement methods and their results

1 Scope

This document introduces five statistical methods for evaluating the precision of binary measurement methods and their results. The five methods can be divided into two types. Both types are based on measured values provided by each laboratory participating in a collaborative study. In the first type, each laboratory repeatedly measures a single sample. The samples measured by the laboratories are nominally identical. The second type is an extension of the first type, where there are several levels of samples.

For each statistical method, this document briefly summarizes its theory and explains how to estimate the proposed precision measures. Some real cases are illustrated to help the readers understand the evaluation procedures involved. For the first and second types of methods, five and three cases are presented, respectively.

Finally, this document compares the five statistical methods.

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 5725-1, *Accuracy (trueness and precision) of measurement methods and results — Part 1: General principles and definitions*

3 Terms and definitions, and symbols

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3534-1 and ISO 5725-1 and the following apply.

ISO and IEC maintain terminological 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/

3.1.1
accordance
probability that two binary measured values be identical when they are taken from the same laboratory

Note 1 to entry: The concept corresponds to the definition of “repeatability” in ISO 5725 and was originally proposed by Reference [3].

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